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The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) submitted a draft processed poultry audit report to China on April 22, 2011 and a final on September 7, 2011. In response China proposed corrective actions on July 15 and September 27, 2011. The published final audit report (October 6, 2011) was amended on September 30, 2011 to include China's proposed corrective actions, in the body of the reports, which addresses the areas of non-compliance FSIS identified within China's processed poultry inspection system. The audit findings for the draft and final audit reports remained unchanged.

A handwritten signature in black ink, appearing to read "Andreas Keller".

Andreas Keller

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Office of International Affairs

OCT 06 2011

FINAL REPORT OF AN AUDIT CONDUCTED IN

THE PEOPLE'S REPUBLIC OF CHINA

DECEMBER 1-21, 2010

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING  
THE PRODUCTION OF PROCESSED POULTRY  
INTENDED FOR EXPORT TO  
THE UNITED STATES OF AMERICA

Food Safety and Inspection Service  
United States Department of Agriculture

## *Executive Summary*

This audit report describes the outcome of an on-site verification audit conducted by the Food Safety and Inspection Service (FSIS) on December 1-21, 2010, to determine whether FSIS could reaffirm that the People's Republic of China (PRC) food safety system governing poultry processing is equivalent to that of the United States (U.S.), with the ability to produce products which are safe, wholesome, unadulterated, and properly labeled. This audit was conducted concurrently with an initial equivalence audit of the PRC's poultry slaughtering inspection system, for which the observed findings are included in a separate report. Representatives from China's Inspection Quarantine (CIQ) offices accompanied the FSIS auditors throughout the entire audit.

The focus of the audit was on the ability of the Central Competent Authority (CCA), the Administration for Quality and Safety Inspection and Quarantine (AQSIQ), to regulate processed poultry production. FSIS reviewed and verified the information provided by the PRC in the completed *Self Reporting Tool* (SRT). Six poultry processing establishments, four government offices, including the CCA, and six laboratories conducting microbiological testing were audited. Determinations concerning the effectiveness of PRC's food safety program focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical Residue Programs, and (6) Microbiological Testing Programs.

The auditors concluded that the CCA was able to meet the principal requirements for the following equivalence component: (3) Sanitation.

Findings of systemic impact were identified within the equivalence components for: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (4) Hazard Analysis and Critical Control Point (HACCP) Systems, and (6) Microbiological Testing Programs. The component (5) Chemical Residue Programs is not addressed in this report because it does not directly apply to the auditing of a poultry processing inspection system, but has been included in the audit of the initial equivalence for poultry slaughter inspection that was conducted simultaneously with this audit.

- The CCA provides limited coordination of its inspection staff as it pertains to the issuance of written training materials and inspection manuals, relying extensively on the provincial Inspection and Quarantine Authorities (CIQ) to develop this guidance. However, the auditors noted that this autonomy resulted in significant variation in the application of national and export poultry standards amongst provinces.
- The CCA does not uniformly verify that poultry processing plants control *Listeria monocytogenes* (*Lm*) in the post-lethality environment.
- The national HACCP standard, GB/T 19538-2004, does not require food producers to establish measures to prevent recurrence in response to a deviation from the critical limit. This does not meet FSIS' equivalence criteria applied to foreign HACCP systems, which are based on the requirements found in 9 CFR 417.

- The national HACCP standard, GB/T 19538-2004, does not require food producers to establish measures to prevent recurrence in response to a deviation from the critical limit. This does not meet FSIS' equivalence criteria applied to foreign HACCP systems, which are based on the requirements found in 9 CFR 417.
- Regulatory oversight of HACCP systems employed by poultry processing plants is not adequate, demonstrated by inadequate design of flow charts and failing to identify biological hazards.
- The CCA utilizes establishment-paid employees to conduct official government inspection duties, such as pre-operational sanitation verification, which constitutes a potential conflict of interest.

In order to demonstrate an equivalent inspection system, the CCA is to submit a comprehensive corrective action plan addressing the specific audit findings outlined in the report for each component. FSIS will evaluate the extent to which the proposed corrective actions sufficiently address the systemic findings identified. Provided the corrective actions are sufficient, China would then be able to certify a list of establishments eligible to ship processed poultry that originated from an approved source to the U.S. However, FSIS may conclude that an additional on-site audit is necessary to verify the adequacy of the corrective actions provided.

This final audit report has been amended on September 30, 2011 to incorporate China's corrective actions in response to the findings in the draft final audit report. China's proposed corrective actions, offered to date, have been inserted into the individual components of the report, which address the non-compliances identified within their food safety system. Additionally, FSIS has conducted an analysis of China's proposed corrective actions and has requested additional supporting documentation.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AHVB	Animal Husbandry and Veterinary Bureau
AQSIQ	Administration of Quality and Supervision and Inspection Quarantine
CCA	Central Competent Authority (AQSIQ)
CFR	Code of Federal Regulations
CIQ	Inspection and Quarantine Authority (Branch and Provincial)
CNAS	China National Accreditation Service for Conformity Assessment
CNCA	Certification and Accreditation Administration
<i>E. coli</i>	<i>Escherichia coli</i>
FSB	Entry-Exit Food Safety Bureau
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
<i>Lm</i>	<i>Listeria monocytogenes</i>
MOA	Ministry of Agriculture
MOH	Ministry of Health
OIA	Office of International Affairs
PPIA	Poultry Products Inspection Act
PRC	People's Republic of China
RTE	Ready-to-Eat
<i>Salmonella spp.</i>	<i>Salmonella</i> species
SSOP	Sanitation Standard Operating Procedures
USDA	United States Department of Agriculture
VIC	Veterinarian-in-Charge

## 1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of the People's Republic of China (PRC) poultry processing inspection system from December 1 through 21, 2010. This audit was conducted simultaneously with a FSIS on-site audit of the PRC's poultry slaughter inspection system, for which the observed findings are included in a separate report.

The audit began with an entrance meeting held on December 1, 2010, in Beijing with the participation of representatives from the Central Competent Authority (CCA) – the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of the PRC (AQSIQ), representatives from the United States Embassy in China, and the FSIS audit team.

## 2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The audit objective was to verify that the PRC's food safety system governing poultry processing is equivalent to that of the United States (U.S.), with the ability to produce and export products that are safe, wholesome, unadulterated, and properly labeled. In pursuit of this objective and prior to the on-site audit, FSIS conducted an extensive review of the information provided by the PRC in the *Self Reporting Tool (SRT) for On-going Equivalence* and accompanying references. These documents provide a comprehensive overview of all the relevant legislation and procedures supporting the poultry processing inspection system.

The FSIS auditors were accompanied throughout the entire audit by representatives from the provincial Inspection and Quarantine Authority (CIQ) or branch CIQ. Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point (HACCP) Systems, (5) Chemical Residues, and (6) Microbiological Testing Programs.

Administrative functions were reviewed at the CCA headquarters in Beijing, five provincial offices, and three branch offices, during which the auditors evaluated the implementation of the management control systems in place, which ensure that the national system of inspection, verification, and enforcement was being implemented as intended.

In order to verify the CCA's ability to provide consistent government oversight, FSIS visited a sample of six poultry processing establishments from a total of eleven identified by the CCA as meeting the U.S. import requirements to see how inspection was being conducted there. The selection of establishments targeted five provinces presenting facilities identified by the CCA as meeting U.S. requirements, thereby providing a representative sample of the PRC's poultry processing inspection system. During establishment visits, particular attention was paid to the extent to which industry and

government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 381.196.

Additionally, six laboratories conducting microbiological testing were audited to verify the CCA's ability to provide adequate technical support to the inspection system.

### Audit Scope Summary

Sectors Audited			Locations
Competent Authority Offices	Central Authority	1	Beijing
	Provincial Offices	5	Shandong, Shenzhen, Jiangsu, Henan, and Hebei
	Branch Offices	3	Qingdao, Sungang, and Puijiang
	Local Offices	6	Zhucheng and Jimo in Qingdao province, Shenzhen in Guangdong province, Shanghai in Jiangsu province, Huangchuan in Henan province, and Dachang Hui in Hebei province.
Microbiological Laboratories		6	<ul style="list-style-type: none"> <li>• Weifang Entry-Exit Inspection and Quarantine Bureau, Shandong</li> <li>• Inspection and Quarantine Technical Center of Shandong Entry-Exit Inspection and Quarantine Bureau</li> <li>• Food Inspection and Quarantine Center Shenzhen Entry-Exit Inspection and Quarantine Bureau (FICS), Shenzhen in Guangdong province</li> <li>• Technical Center For Animal, Plant and Food Inspection and Quarantine, Shanghai</li> <li>• Henan Entry-Exit Inspection and Quarantine Bureau</li> <li>• Inspection &amp; Quarantine Technical Center of Hebei Entry-Exit Inspection And Quarantine Bureau</li> </ul>
Poultry Processing Establishments		6	<ul style="list-style-type: none"> <li>• Shandong Delicate Food Co., Ltd</li> <li>• Chia Tai Co., Ltd</li> <li>• Henan Huaying Agriculture Development Co., Ltd</li> <li>• Husi Food Company Ltd in Hebei</li> <li>• McKey Food Services Limited in Shenzhen, in Guangdong province</li> <li>• Husi Food Company Ltd in Shanghai</li> </ul>

### **3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS**

The audit was conducted under the specific provisions of the United States' laws and regulations, in particular:

- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.)
- The Poultry Products Inspection Regulations (9 CFR 381.196)

The audit standards included all applicable legislation and procedures submitted to FSIS by the PRC as part of the document review process.

### **4. BACKGROUND**

This audit to reassess FSIS' prior determination of equivalence for China's poultry processing inspection system was conducted in conjunction with FSIS' initial equivalence audit of the PRC's slaughtered poultry inspection system. Under the poultry processing equivalence determination, the PRC was eligible to export only processed products derived from birds slaughtered in the U.S. or from another country eligible to export slaughtered poultry to the U.S. The USDA's Animal and Plant Health Inspection Service (APHIS) has affirmed PRC to be affected with highly pathogenic Avian Influenza subtype H5N1 and Exotic Newcastle Disease and therefore, prohibits PRC from exporting raw poultry to the U.S. APHIS is currently conducting a risk assessment for these animal diseases, and until APHIS lifts these disease restrictions PRC cannot export raw poultry products to the U.S.

The PRC first requested an initial equivalence determination of its poultry processing inspection system in May 2004, for which FSIS conducted on-site audits in 2004 and 2005. In 2006, the PRC was added to the list of countries eligible for export to the U.S. with the stipulation that only processed poultry products derived from flocks slaughtered under the U.S. inspection system, or from another country eligible to export slaughtered poultry products to the U.S., would be permitted. However, as no processed poultry was ever exported to the U.S., FSIS suspended the PRC's eligibility based on its inability to verify on-going equivalence through its usual mechanisms, which include port-of-entry (POE) testing and on-site audits. Furthermore, the introduction of the PRC's Food Safety Law (FSL) 2009 necessitated that FSIS evaluate the impact that this new law had on its equivalence determination for processed poultry. The current audit constitutes an integral step in the process of re-affirming the on-going equivalence status of the PRC's processed poultry inspection system and reinstating export eligibility.

In the 2004 and 2005, FSIS audits of the PRC identified concerns regarding payment of official inspectors, enforcement of requirements for the maintenance of sanitary conditions, and the implementation of HACCP programs at establishments. The CCA proffered a corrective action plan that was accepted by FSIS and included in the final audit report.

After conducting a comprehensive analysis of all relevant legislation supporting the PRC's poultry processing inspection system, FSIS proceeded with the current audit. Upon re-affirming equivalence for their poultry processing inspection system, the PRC would then be able to certify a list of establishments eligible to export processed poultry that originated from an approved source to the United States.

## 5. GOVERNMENT OVERSIGHT

The first of the six components that the FSIS auditors reviewed was Government Oversight. The evaluation included a review and analysis of documentation submitted as support for the responses provided by the CCA in the SRT and observations gathered during the on-site audit.

The FSIS auditors assessed the extent to which the PRC's poultry processing inspection system is organized and administered by the government of the PRC and confirmed that the State Council of the PRC delegates AQSIQ with the authority to administer the poultry processing inspection system for exports. Consequently, AQSIQ serves as the CCA responsible for the safety of food products, promulgation of regulations on food inspection, and has sole authority to enforce the laws and regulations of the export system. Registration and certification of import/export food enterprises is conducted by two major bureaus of the CCA, namely the Certification and Accreditation Administration (CNCA) and the Entry-Exit Food Safety Bureau (FSB) which verify that establishments fulfill official requirements prior to being granted certification to export. Funding for CCA operations is provided by the central government and supplemented by fees assessed by the government on exported products.

In addition, the auditors assessed the manner through which the Ministry of Agriculture (MOA) and the Ministry of Health (MOH) interact with the CCA to maintain appropriate regulation of the production of poultry products for export. As part of this arrangement, the China National Accreditation Service for Conformity Assessment (CNAS) together with the CCA, have promulgated the national standard that provides the general requirements for laboratory quality systems.

FSIS auditors observed that the CCA delegates to 35 inspection and quarantine bureaus (CIQ) located throughout the country the responsibility to implement inspection of animals and animal products, and regulate poultry processing activities at establishments producing products for export. CIQ officials are assigned to enforce laws and regulations governing poultry inspection in official establishments. However, the FSIS requirement of ultimate control and supervision over inspectors' verification of sanitation activities was not consistently being met since the CCA allows establishment-paid inspectors to conduct regular pre-operational sanitation verification at processing establishments. The use of establishment-paid inspectors conducting inspection related activities can result in biased decisions leading to the export of unsafe poultry products to the U.S. This arrangement constitutes a conflict of interest, and does not meet the requirements for *ultimate control and supervision over the official activities of all employees of the system* articulated by the FSIS import regulations (9 CFR 381.196).

The CCA disseminates information throughout the three sectors (government offices, establishments, and laboratories) pertaining to regulatory and administrative affairs, either electronically or via hard copies. The auditors noted that, in many cases, the provincial CIQs autonomously oversee the functions of the inspection system by designing and implementing inspection-related procedures in accordance with national standards, in addition to those standards imposed by other importing countries. However, FSIS concluded that this autonomy creates significant variation in the application of these standards amongst provinces. For example, FSIS auditors observed that the CCA does not verify in a uniform manner that poultry processing plants are controlling *Listeria monocytogenes (Lm)* in the post-lethality environment. The lack of standardized inspection procedures, and thus the lack of government oversight of its inspection personnel, is a recurring finding within the PRC's system, as further evidenced in subsequent portions of this report.

The CCA and CIQs provide training to CIQ official inspectors on food safety, sampling procedures, export requirements, sanitation, and HACCP systems. Newly hired inspection personnel complete initial inspection training and after an evaluation receive on the job training prior to reporting to their final assignments. On-going training is coordinated primarily by the provincial CIQs. However, the FSIS auditors noted that CIQ official inspectors did not demonstrate an ability to verify that the implementation of HACCP and microbiological testing programs was consistent with government requirements. While the auditors observed that the inspection system presented provisions for training of personnel, these findings indicated that employee training was not at a level to ensure consistent performance, as previously mentioned and covered in the HACCP Systems component.

While the current audit indicated that the PRC's poultry processing inspection system is organized and administered by the government, the systemic findings associated with this component indicate an inability for the CCA to apply these standards uniformly at establishments intending to export to the U.S., and fails to meet the core requirements for an equivalent inspection system outlined in 9 CFR 381.196.

Therefore, FSIS concluded that the PRC's inspection system does not meet the requirement for this equivalence component.

### **CHINA'S PROPOSED CORRECTIVE ACTIONS**

- ***Standardized Inspection Procedures***

*AQSIQ issued two manuals:*

- 1) *Inspection and Quarantine Manual for Poultry Exported to America manual. This manual is expected to make unified requirements on inspection procedures and supervisors in export of cooked poultry meat products to the U.S.*
- 2) *Microorganism Monitoring Program for Export Poultry Products, manual which will make unified provisions in monitoring both export poultry meat products and processing environment.*

*Based on these two manuals AQSIQ will carry out related trainings on the inspection and quarantine regulation of export poultry products.*

- ***Establishment-Paid Inspectors to Conduct Official Inspection Duties***

*At present, the Chinese requirements of pre-operational check for cooked poultry meat processing establishments are that:*

- 1) Establishments shall conduct daily pre-operational sanitary check, and*
- 2) CIQ official also shall carry out on-site verification of the establishments' pre-operational inspection and review related records in daily supervision. The reason why FSIS auditor comes to the conclusion that CCA utilizes establishment-paid employees to conduct official duties is that they mistake the pre-operation check by establishment the duty carried out by CIQ during the on-site audit.*

*The AQSIQ has formulated the Inspection and Quarantine Manual for Poultry Exported to America, which has made detailed provision on daily inspection and pre-operational examination: (See 2.3.1.1 Routine supervision and management). Training will also be enhanced to avoid misunderstanding of individual inspectors.*

## **6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that the FSIS auditors reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the regulatory framework utilized by the CCA to impose requirements equivalent to those governing the system of processed poultry inspection organized and maintained in the U.S.

The result of the off-site comprehensive document review indicated that the inspection system provides requirements for processed poultry inspection activities, establishment construction, control over inedible and condemned materials, as well as daily inspection and periodic supervisory reviews of official establishments.

The PRC provides a statutory framework outlining the requirements of its poultry inspection system against the standards promulgated by the CCA, which includes separation of domestic and exported products and periodic supervisory visits. The current audit identified a systemic finding that compromises the ability of the CCA to verify the consistent production of wholesome poultry products intended for export to the U.S. The auditors noted the use of establishment-paid inspectors conducting official activities, such as pre-operational sanitation verification at processing establishments constitutes a potential conflict of interest. This finding was previously discussed in the Government Oversight equivalence component.

Therefore, FSIS concluded that the PRC's inspection system does not meet the requirement for this equivalence component.

## 7. SANITATION

The third of the six equivalence components that the FSIS auditors reviewed was Sanitation. FSIS requires that the inspection system provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures.

FSIS auditors reviewed legislation, regulations, and official instructions and ascertained that the CCA exercises its legal authority to require sanitation and sanitary handling of products. An assessment of official regulatory oversight and compliance maintained by the establishments was conducted in accordance with the following issuances: AQSIQ Directive No. 20, 2002: *Regulation on Administration of Sanitary Registration and Enrollment for Establishments of Food for Export* and GB/T 20094-2006, AQSIQ National Standard: *Code of Hygienic Practice for Registration on Abattoir and Meat Processing Establishments*. These documents address the prevention of insanitary conditions and direct contamination of products. Specific requirements include provisions for the construction, ventilation, and maintenance of facilities, and the need to establish documented training programs for establishment personnel. These issuances also require operators to conduct documented internal audits of their sanitation program biannually.

The auditors' assessment of the design and implementation of sanitation programs at the establishments intending to export to the U.S. included a review of monitoring records, documented corrective actions, training program for employees, and an assessment of the actual conditions in the production areas. The auditors observed that the regulations of the system places the burden of maintaining sanitary standards upon the producer, and operators are required to conduct product contact surface testing to demonstrate the adequacy of the sanitation procedures. The review of inspection records and interviews with AQSIQ officials indicated that these individuals were proficient in conducting verification and enforcement activities related to sanitation.

One area for improvement identified by the auditors concerned the manner in which the establishments conducted the aforementioned biannual assessments, conducted in accordance with Section 8, Article 16 of AQSIQ Directive No. 20, which states, "An internal audit system should be set up in the establishment. The internal audit should be conducted once every six months, and a management audit should be carried out once a year, and records should be kept." These audits are supplementary to those routine activities related to monitoring, recordkeeping, and review of records which occur on a daily basis as part of an establishment's sanitation program and found to comply with FSIS standards. However, a review of the audit records indicated that these reviews simply reflected additional monitoring of the sanitation program, as indicated by the identification of individual failures to adequately maintain or clean equipment, rather than a systemic examination as to whether these activities and related results comply with the planned objectives, which are typically associated with the term "audit." Neither establishment personnel nor inspection officials interviewed were able to describe the CCA's expectations for the type of audit methodology to be applied or the nature of

conclusions reached, other than what is included in Section 8 of the referenced document. Consequently, this situation represents a need for further written guidance from the CCA to ensure that the implementation and verification of this national standard occurs as intended.

In accordance with the above findings, the FSIS concluded that the CCA effectively implements its requirements for sanitation and sanitary handling of poultry products intended for export to the U.S. As a result, the PRC meets the requirements for this equivalence component.

## **8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

The fourth of the six equivalence components reviewed by FSIS was HACCP systems. The inspection system must require that each official establishment develop, implement, and maintain a HACCP plan.

The auditors verified that the CCA has issued regulations that require that each official establishment develop, implement, and maintain a HACCP system. The auditors evaluated the design and implementation of HACCP programs at six certified processing establishments against the regulatory requirements prescribed in GB/T 19538-2004, *AQSIQ HACCP System and Guidelines for its Application*, 2004; and SN/T 1252-2003, *HACCP System and Guidelines for its Application*. The auditors observed that the CCA exerts its legal authority by requiring operators to comply with HACCP system rules.

Concerning the identification of pathogens of concern within the audited establishments' hazard analysis, the auditors observed that Avian Influenza Virus (AIV) is recognized as a hazard, and as a result, multiple interventions are put in place to control its occurrence. Producers of processed poultry products are required to obtain raw poultry products from sources identified by the PRC as AIV negative, and all processed poultry must undergo a heat treatment of at least 74° C to destroy the virus.

The auditors observed that the HACCP requirements are reinforced by articles of the Food Safety Law (FSL) of 2009 which mandate that producers ensure that food raw material, food additives, and food-related products received at their establishments be accompanied by food safety certificates. Producers are further required to verify the license and compliance certification of their suppliers.

The auditors made multiple significant findings:

- Failure to specifically identify *Lm* as a potential biological hazard likely to occur in the post-lethality processing environment in their hazard analysis. However, establishments did have sanitary controls in place controlling the post-lethality environment.
- The stabilization step for heat-treated products was not identified in the hazard analysis in some establishments.

- In one establishment, the processing steps were omitted from the product flowchart, and as a result, the missing steps were not included in the hazard analysis of the entire process. The CIQ officials did not recognize inadequacies of the HACCP plans.
- The national standard outlining requirements for HACCP systems (GB/T 19538-2004) does not require that producers include preventive measures as part of the corrective actions to deviations from critical limits.

The significant omission concerning preventive measures within the PRC's HACCP legislation, in addition to the lack of regulatory oversight identified at establishments, constitute systemic findings that compromise the CCA's ability to implement their HACCP requirements, and ultimately ensure the consistent production of safe poultry products intended for export to the U.S.

Therefore, FSIS concluded that the PRC's inspection system does not meet the requirement for this equivalence component.

### **CHINA'S PROPOSED CORRECTIVE ACTIONS**

- ***HACCP-Establish Preventive Measures***

*The Chinese national standard GB/T19538-2004 is equivalent to the standards of the Codex Alimentarius Commission (CAC/RCP1-1969, REV3 1997, AMD 1999), in which corrective actions contain precautionary measures that should be taken and the requirements of preventing recurrence. It is explicitly required in China's training materials on safety and hygiene quality management on export food production enterprises that companies must take measures to prevent the departure from happening again.*

- ***HACCP - Issues Regarding Risk Identification***

*China is formulating the guidance of risk analysis and control for heat-processed poultry products to guide enterprises to establish a HACCP plan, especially the risk analysis of the heat stabilization process and the identification and control of *Listeria monocytogenes* in the environment after heat-processing. This document will be provided to FSIS as soon as possible.*

## **9. CHEMICAL RESIDUES**

The fifth of the six equivalence components reviewed by FSIS was Chemical Residues. The inspection system must have a chemical residue control program, organized and administered by the national government, which includes random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

This component does not directly apply to the auditing of a poultry processing inspection system, but has been included in the audit of the initial equivalence for poultry slaughter inspection that was conducted simultaneously with this audit.

## 10. MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditors reviewed was Microbiological Testing Programs. This component pertains to regulatory requirements for the inspection system to have a microbiological testing program, organized and administered by the national government. Establishments certified for export to the U.S. are to employ control measures to prevent adulteration of both non post-lethality exposed ready-to-eat (RTE) products and post-lethality exposed RTE products by *Listeria monocytogenes* (*Lm*) and *Salmonella spp.* Furthermore, the CCA is to conduct verification sampling and testing for *Lm*, *Listeria spp.* or *Listeria*-like organisms in the post-lethality exposed RTE products, product contact and environmental surface samples, and *Salmonella spp.* in the RTE products, at a frequency that ensures that the establishments' control measures are effective in controlling these pathogens.

The auditors' review of this component indicated that the CCA lacked a clear understanding of FSIS's RTE policy as outlined in 9 CFR 430.1. The confusion was created by the CCA's assumption that fully-cooked product that is frozen prior to shipment is not considered RTE. The auditors' on-site review confirmed that these products are classified as RTE by FSIS' standards. The auditors further explained that freezing did not affect a product's RTE status, as they had received a lethality step for cooking and could be later consumed after minimal reheating. The lack of clear guidelines is a significant issue as it relates to FSIS' ability to conclude the effective implementation of the PRC's food safety systems for RTE product. In order to export cooked poultry products to the U.S., the CCA needs to demonstrate clear written guidance to inspection officials and food operators to ensure that proper verification procedures are applied to all exported products meeting FSIS' definition for RTE.

The FSIS auditors observed that the audited establishments were testing for *Lm*, *Listeria* species, or *Listeria*-like organisms in the product and processing environment as mandated by the PRC. However, the CIQ officials did not verify that the methods used by the establishments to test either the product or environmental samples were fit for purpose. This was evident by the failure of official veterinarians to verify the testing methods employed by the establishments, such as the validation of method for product and environmental sample matrices. The FSIS auditors verified that cooked poultry products were being sampled by official inspection personnel to be tested for *Lm* and *Salmonella spp.* at the government laboratories. Prior to and during the audit the PRC discussed a zero tolerance policy for *Lm* and *Salmonella spp.* in RTE product. However, the audit team was unable to identify any specific legislation or written procedures describing this zero tolerance policy. The legislation *AQSIQ Order No. 26: Measures for the Administration of the Inspection and Quarantine of Meat Products at Entry and Exit, 2002*, discusses that a product testing positive for "harmful and noxious substances" should be barred from export. However, this legislation fails to specifically define the

terms “harmful and noxious substances.” FSIS requests that the CCA clarify and submit additional information demonstrating that the PRC has a zero tolerance policy for *Lm* and *Salmonella spp.* in RTE product.

The auditors observed that three of the five provincial CIQ’s audited were not conducting environmental testing to ensure that the establishments’ control measures were effective in controlling *Lm* in the post-lethality processing environment. When the auditors discussed this inconsistency with the CCA at the exit meeting, the CCA stated that national experts were drafting the necessary guidance needed to ensure a uniformly implemented environmental sampling program, which would verify the effectiveness of *Lm* control in post-lethality exposed RTE products. To date the aforementioned document has not been provided by the PRC.

During the laboratory visits, verification focused on the adequacy of analysts’ qualifications, sample receiving and handling, analytical methodology, data reporting, maintenance of facilities and equipment, and corrective actions. Even though export to the U.S. was not yet occurring, the auditors verified that these laboratories possessed the technical capacity to ensure that accurate product testing of product destined for the U.S. occurred. The FSIS auditors verified that the PRC’s microbiological testing laboratories are ISO 17025 accredited and are well equipped to provide technical support to the poultry inspection system, and that laboratory management is familiar with the FSIS testing requirements. The current analytical test portions for both *Lm* and *Salmonella spp.* is 25g. FSIS requires a minimum of 25g and 325g analytical test portion for *Lm* and *Salmonella spp.*, respectively. The CCA indicated that upon initiation of export to the U.S., the laboratories will meet FSIS requirements for analytical test portions and will test using the FSIS approved methods, ISO 11290-1: 1996-12-15 and ISO 6579:2002 for *Lm* and *Salmonella spp.*, respectively.

The lack of clear guidance concerning the definition of RTE product, and the inconsistent application of environmental testing programs greatly compromises the CCA’s ability to implement an effective microbiological testing program. Consequently, the PRC’s inspection system was unable to demonstrate the same level of protection as that provided by the U.S. system to control pathogenic microorganisms typically associated with processed poultry products.

Therefore, FSIS concluded that the PRC’s inspection system does not meet the requirement for this equivalence component.

### **CHINA’S PROPOSED CORRECTIVE ACTIONS**

- ***Microbiology Testing Program***

*China has now fully understood the definition of Ready to Eat (RTE). Previously, poultry products in China are processed in accordance with the requirements of fully cooked products, heating process is strictly controlled and contamination control measures are taken in cooking and cooked areas; and microorganism is tested through sampling from*

*final products, which can ensure that safety of the final products. This conforms to requirements of RTE products in the United States, and is also equivalent.*

*AQSIQ has formulated the Microorganism Monitoring Program for Export Poultry Products, which specifically required the method to monitor microorganisms including Listeria monocytogenes (Lm) in both export poultry meat products and processing environment., and to verify the method(See appendix 6 of the monitoring program).*

*AQSIQ Order No. 26 was replaced by Order No. 136 and was implemented on June 1, 2011, and according to the definition and connotation, such materials include Listeria, Salmonella and other pathogenic microorganisms Article 31 of the regulations has clearly specified that "inspection and quarantine agencies shall carry out sample tests based on risk analysis on for pathogenic microorganisms, agriculture and veterinary drug residue as well as environmental pollutants and other toxic or harmful substances in exported meat products; verify and monitor quality and safety control system during production process of exported meat". in addition, Order No.40 issued by China State Quality Inspection Administration in 2002 defines "poisonous and harmful materials", which refer to biological, physical and chemical materials which can cause harm to agriculture and animal husbandry fishery production, human health and ecological environment. According to the definition and connotation, such materials include Listeria, Salmonella and all other pathogenic microorganisms.*

*In order to achieve export of cooked poultry products to the United States as soon as possible, China is willing to take the U.S.'s opinions and AQSIQ has formulated the Microorganism Monitoring Program for Export Poultry Products, which clearly require to test Listeria and salmonella, and has a zero tolerance for Lm and Salmonella in cooked poultry products (See attachment 2 of the monitoring program).*

*AQSIQ has formulated the Microorganism Monitoring Program for Exported Poultry Products, which requires 325g will be the minimum quantity for detecting the Salmonella in the exported cooked poultry products (See attachment 2 of the monitoring program)*

*China believes that in accordance with the relevant requirements of China's food safety, food-born pathogens must not be detected in meat products. The CIQs at all levels are responsible for testing final products, meanwhile the establishments shall test each lot of final products, and only qualified products that are free from pathogens are allowed for export. Although CIQ has no uniform measures for verifying the control of Listeria in the post lethality environment, it has resulted in the same effects as requirements of the US.*

*In order to achieve export of cooked poultry products to the United States as soon as possible, China is willing to take the U.S.'s approach to make unified provisions, and China has also formulated the Microorganism Monitoring Program for Export Poultry Products, which require uniformly to monitor microorganisms including Listeria monocytogenes (Lm) in both export poultry meat products and processing environment (See attachment 2 of the Monitoring plan). And relevant trainings are planed.*

## 11. EXIT MEETING

An exit meeting was held on December 21, 2010, in Beijing with AQSIQ. At this meeting, the FSIS auditors presented the preliminary findings of the audit.

## 12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

FSIS concluded that the CCA was able to meet the principal requirements for the Sanitation equivalence component. The assessment of actual establishment conditions in association with inspection records and interviews with AQSIQ officials indicated that these individuals were proficient in conducting verification and enforcement activities related to sanitation. However, the requirements for internal audits conducted bi-annually by establishments in accordance with Section 8, Article 16 of AQSIQ Directive No. 20 were not clearly defined, thereby representing a need for further written guidance from the CCA to ensure that the implementation and verification of this national standard occurs as intended.

Findings of systemic impact were identified within the equivalence components for: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (4) Hazard Analysis and Critical Control Point (HACCP) Systems, and (6) Microbiological Testing Programs. The component (5) Chemical Residue Programs is not addressed in this report because it does not directly apply to the auditing of a poultry processing inspection system but has been included in the audit of the initial equivalence for poultry slaughter inspection that was conducted simultaneously with this audit.

- The CCA provides limited coordination of its inspection staff as it pertains to the issuance of written training materials and inspection manuals, relying extensively on the provincial CIQ to develop this guidance. However, the auditors noted that this autonomy resulted in significant variation in the application of national and export poultry standards among the provinces.
- The CCA does not uniformly verify that poultry processing plants control *Lm* in the post-lethality environment.
- The national HACCP standard, GB/T 19538-2004, does not require food producers to establish measures to prevent recurrence in response to a deviation from the critical limit. This does not meet FSIS' equivalence criteria applied to foreign HACCP systems, which are based on the requirements found in 9 CFR 417.
- Regulatory verification of HACCP systems employed by poultry processing plants is not adequate, demonstrated by establishments having flow charts that are inadequately designed and failing to identify biological hazards.
- The CCA utilizes establishment-paid employees to conduct official inspection duties, such as pre-operational sanitation verification, which constitutes a potential conflict of interest.

In order to demonstrate an equivalent inspection system, the CCA has provided corrective actions addressing specific audit findings outlined in the report. FSIS has

evaluated the proposed corrective actions and will be requesting further information to assure that FSIS audit findings are sufficiently addressed. Provided the corrective actions are sufficient, FSIS may determine if an additional on-site audit is necessary to verify the adequacy of the corrective actions provided. Once all outstanding issues have been resolved, China would then be able to certify a list of establishments eligible to export processed poultry that originated from an approved source to the United States.

**FSIS ANALYSIS of CHINA'S PROPOSED CORRECTIVE ACTIONS:**

FSIS has requested the following information in response to analysis of China's proposed corrective actions.

1. Documentation that food producers must implement corrective action to ensure that the cause of the deviation is identified and eliminated and that measure to prevent recurrence are established (FSIS Regulations 9 CFR 417.3(a) (3)).
2. Documentation that demonstrates the content of training materials relevant to corrective action verification, and includes training to assess measures that prevent recurrence of a deviation.
3. Guidelines for hazard analysis and control measures for when producers of cooked poultry meat specifically identify Lm as a potential biological hazard if the product is exposed to the post-lethality environment.
4. Guidelines for hazard analysis and control measures that relate to the stabilization step, for heat-treated products, and that the stabilization step meets the performance standards for preventing the growth of spore-forming bacteria (9 CFR §§ 381.150(a)(2)).
5. Documentation and training materials that demonstrate inspection personnel have adequate knowledge regarding verification activities of HACCP plans to ensure the hazard analysis addresses potential hazards that are reasonably likely to occur.
6. A copy of the AQSIQ Order No. 136 implemented on June 1, 2011.
7. Provide all documentation and training material relevant for inspection and supervisory personnel of export poultry products, such as:
  - A developed training plan,
  - A defined training manner,
  - Confirmation of training class hours,
  - Training material associated with "Inspection and Quarantine Manual for Poultry Exported to America,"
  - Training material associated with "Microorganism Monitoring Program for Export Poultry Products,"
  - Strengthened training of relevant inspectors before working,

- A process for continuous trainings and making assessments of training process,
- Enhanced capability of inspector verification activities and verifying the effectiveness of supervision and inspection on enterprises.

**Audit Team:**

Francisco Gonzalez, DVM  
Senior Program Auditor

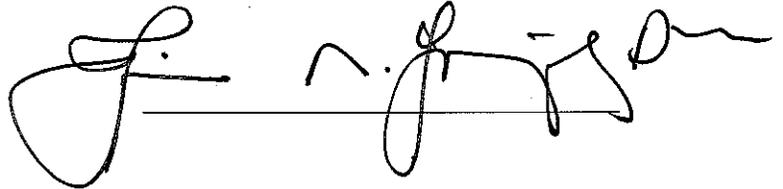
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**13. ATTACHMENTS TO THE AUDIT REPORT**

Relevant sections of China's proposed corrective actions in response to the findings in the draft final audit report are included in this amended version of the report. A completed translated version of China's comments to the draft final audit report is attached. Any additional responses from China will be uploaded on the website as they become available.

Attachment 1

OCT 06 2011

Comments on the draft reports of US's audit on Chinese poultry slaughter and thermal processing system – Received on July 15, 2011

The letter about the submission of the comments on the draft reports of US's audit on Chinese poultry slaughter and Thermal processing system

Dear Director, Andreas Keller:

We received your two draft audit reports respectively on China poultry slaughter and thermal processing system on 25 April, which are submitted on 22 April.

Five CIQs audited by US in December 2010 are organized to review and comment your two draft audit reports. Both sides have made a preliminary communication and opinion exchange by conference call on 28 April. In the conference call China has made its position clear and US side was also aware of some problems arose from misunderstanding and expect China to submit comments and supporting documents so as to modify the misunderstanding parts of the draft reports.

China once again clarify the position as follows: We expect US to be more sincere to solve the problem of importing heated poultry products from China to US, and this audit can be considered to be carried out by US based on the concept of identity not equivalence, as well as some isolated case is magnified into systemic deficiencies in audit reports. After review, we found that the problems come up with in the reports fall into two situations as follows: **one is that the problem is not actual**, for example, China is not fully aware of FSIS's requirement of ready-to-cook poultry and the potential benefit conflict occurred when the establishment-paid inspector perform the check of pre-operation, **the other is that the problem is isolated and not systemic deficiency, and China will take effective measures to correct them**. For example, CIQ didn't take appropriate enforcement action when establishment monitoring is not effective in identifying deviations from critical limits when they occur, L. monocytogenes isn't determined as potential biological hazard for the environment after heat process, there is no official standard method to assign the inspection personnel to slaughterhouse based on production line rates or inspection workload and official didn't verify the test methods adopted by establishments on samples of product and food contact surface. To facilitate the work of the United States, China has commented the problems in the two draft audit reports one by one and propose equivalent or identical correction measurements to U.S.(Annex 1.2).

China expect U.S. to make proper modification of its audits reports considering its concerns in the comments and keep the legislative process going, which is suspended in 2005 due to the interference of US congress, to permit importing heated poultry products from China, which are produced from the live poultry raised in China and put China in the list of countries permitted to export heated poultry product to US.

Looking forward to the early U.S. response.

Sincerely.

Annex: 1. Comments on the Draft Report of the U.S.'s Audit on Chinese Heated Poultry Products Control System

2. Comments on the Draft Report of the U.S.'s Audit on Chinese Poultry Slaughter Control System

Director, Food Safety Division I, Import and Export Food Safety Bureau

China State General Administration for Quality Supervision and Inspection and Quarantine, the People's Republic of China

June 15, 2011

CC: Mike Wu, Commissioner of the Embassy of United States of America in China, Economic and Commercial Counsellor's Office of Chinese Embassy in the United States

## Annex 1:

### Comments on the Draft Report of the U.S.'s Audit on Chinese Heated Poultry Products Control System

#### I. Executive Summary

1. — **The report is written that** "the auditors concluded that the CCA was able to meet the principal requirements for the following equivalence component: (3) Sanitation. Findings of systemic impact were identified within the equivalence components for: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (4) Hazard Analysis and Critical Control Point (HACCP) Systems, and (6) Microbiological Testing Programs. The component (5) Chemical Residue Programs is not addressed in this report because it does not directly apply to the auditing of a poultry processing inspection system, but has been included in the audit of the initial equivalence for poultry slaughter inspection that was conducted simultaneously with this audit".

**Evaluation and response of China:** Although there are problems that the Chinese side lacks the standardized methods of determining the number of inspectors allocated in slaughter plants according to production line speed and inspection capacity, authorities do not validate the testing methods of establishments in testing products or environmental samples, and HACCP's establishment, implementation and maintenance are not perfect, these are all individual, occasional, not systemic ones. Regarding HACCP, the reports of the U.S. inspection in China in 2004 and 2005 described that "All establishments approved to export poultry products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program. The HACCP programs were reviewed during the on-site audits of the four establishments. Three establishments had adequately implemented the HACCP basic requirements. In some establishments, the following deficiencies were noted:....."Please make appropriate modifications with accurate presentation.

2. — **The report is written that** "The CCA provides limited coordination of its inspection staff as it pertains to the issuance of written training materials and inspection manuals, relying extensively on the provincial Inspection and Quarantine Authorities (CIQ) to develop this guidance. However, the auditors noted that this autonomy resulted in significant variation in the application of national and export poultry standards amongst provinces."

—**Evaluation and response of China:** *Inspection and Quarantine Manual for Poultry Exported to America* formulated by China's Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) is organized and implemented by Inspection and Quarantine Bureaus directly under the AQSIQ. China believes that although slightly differences exist in some specific practices by these units, there are not significant differences. The current practice can ensure product quality and safety. Please make appropriate modifications in this section based on the factual situation.

In order to achieve export of cooked poultry products to the United States as soon as possible, the AQSIQ has formulated the *Inspection and Quarantine Manual for Poultry Exported to America*, which makes unified requirements on inspection procedures and supervisors in export of cooked poultry meat products to the U.S.; and has formulated the *Microorganism Monitoring Program for Export Poultry Products*, which makes unified provisions in monitoring both export poultry meat products and processing environment, and will carry out related trainings on the inspection and quarantine regulation of export poultry products.

3. —**The report is written that** "The CCA does not uniformly verify that poultry processing plants control *Listeria monocytogenes* (Lm) in the post-lethality environment."

—**Evaluation and response of China:** At present, the AQSIQ has uniformly require CIQs to test *Listeria monocytogenes* in export products, and require establishments to test and self-control both products and processing environments. But according to the regulations of the U.S., the Chinese authorities shall monitor *Listeria* in post-lethality environment and verify enterprises' supervision. Although there are no clearly defined provisions that the CIQ shall monitor related microorganisms in environment, some of CIQs did carry out *Listeria* monitoring in post-lethality environment. China believes that in accordance with the relevant requirements of China's food safety, food-born pathogens must not be detected in meat products. The CIQs at all levels are responsible for testing final products, meanwhile the establishments shall test each lot of final products, and only qualified products that are free from pathogens are allowed for export. Although the CIQ has no uniform measures for verification the controlling of *Listeria* in post-lethality environment, it has resulted in the same effects as the requirements of the U.S. Please make appropriate modifications based on the factual situation.

In order to achieve export of cooked poultry products to the United States as soon as possible, China is willing to take the U.S.'s approach to make unified provisions, and China has also formulated the *Microorganism Monitoring Program for Export Poultry Products*, which require uniformly to monitor microorganisms including *Listeria monocytogenes* (Lm)

in both export poultry meat products and post-lethality environment(See **attachment 2 of the Microorganism Monitoring Program for Export Poultry Products**). And the relevant trainings are planed.

4. —**The report is written that** “The national standard outlining requirements for HACCP systems (GB/T 19538- 2004) does not require that producers include preventive measures as part of the corrective actions to deviations from critical limits.”

—**Evaluation and response of China:** the report is not accurate. The reasons are as follows:

1.The National Standard GB/T 19538-2004, equivalent to the international standard of Codex Alimentarius Commission (CAC / RCP 1-1969, REV 3 1997, AMD 1999), is adopted and promoted in many countries in the world in line with international practice.

2.The definition of 3.4 "corrective actions" is made in the National Standard GB/T19538-2004 that corrective actions must be taken in case of deviations from critical limits. According to definition of the standard and related training materials [such as training materials about *China's Export Food Hygiene Registration Management Guide* (P108, China Foreign Economic and Trade Press 2000, ISBN 7-8004-797-0), detailed description has been made about corrective actions]. Its corrective action includes meaning of and requirements on taking preventive measures from the recurrence of deviations, which in fact has also been proposed in the U.S. 9 CFR PART 417.3.

3. The FSIS has audit the Chinese system in 2004 and 2005, including the establishment, implementation and **maintenance** of HACCP system, also Chinese standards and regulatory requirements, but nothing had mention in the final report that the national standard GB/T 19538-2004 did not meet the relevant requirements of the FSIS.

4. Most of authorities consider that the “Preventive measures” is included in the “Corrective Actions” . For example, in the HACCP regulations of juice and seafood proposed by FDA, corrective actions are required to be taken in case of any deviation from critical limits, and are not **specifically addressed** which to take preventive measures against deviations from critical limits.

5. This evaluation is "equivalency" rather than "identical". Corrective actions including "preventing a recurrence" are included in most of China's training materials and specifically implemented by establishments.

6. The deficiency of no-preventing recurrence measures covered by some establishments found by FSIS in the audit report is only an individual issue rather than problem of national standard itself.

In summary, China believes that the requirements of national standard GB/T19538-2004 have equivalency with the ones of the FSIS PART 417.

5. —**The report is written that** “Regulatory verification of HACCP systems employed by poultry processing plants is not adequate, demonstrated by establishments having How charts that are inadequately designed and failing to identify biological hazards”.

—**Evaluation and response of China:** China is developing hazard analysis and control measures guidelines of cooked poultry meat, which specifically identify Lm as a potential biological hazard likely to occur in the post-lethality environment in the hazard analysis. It will guide establishments to conduct a comprehensive hazard analysis on each processed products to further improve the HACCP plan and strengthen training and supervision on the CIQ supervisors.

6. —**The report is written that** “The CCA utilizes establishment-paid employees to conduct official inspection duties, such as pre-operational sanitation verification, which constitutes a potential conflict of interest”.

—**Evaluation and response of China:** At present, the Chinese requirements of pre-operational check for cooked poultry meat processing establishments are that establishments shall conduct daily pre-operational sanitary check, and CIQ official also shall carry out on-site verification of the establishments’ pre-operational inspection and review related records in daily supervision. The reason why FSIS auditor come to the conclusion that CCA utilizes establishment-paid employees to conduct official duties is that they mistaked the pre-operation check by establishment as the duty carried out by CIQ during the on-site audit.

China learned the US’s daily check requirements, including what to be checked, frequency and who check. China does not allow establishment-paid personnel to perform the official regulatory functions, including pre-operational inspection and daily inspection. The U.S. auditor found that individual CIQ personnel did not understand thoroughly daily inspection, as the United States mentioned in the exit meeting that a CIQ official in a province of the five provinces had a bias understanding, but the issue of individual can not represent the whole of China; In addition, the misunderstanding of CIQ official is the monitoring frequency for cooked products processing establishments rather than the implementation body. Therefore, it is not proper for auditors to conclude that establishment-paid employees conduct official daily inspection and pre-operational examination in cooked products processing establishments.

## **I. Background (Article 4 in the Review Report)**

7. —**The report is written that** “The PRC first requested an initial equivalence determination of its poultry processing inspection system in May 2004, for which FSIS conducted on-site audits in 2004 and 2005. In 2006, the PRC was added to the list of countries eligible for export to the U.S. with the stipulation that only processed poultry products derived from flocks slaughtered under the U.S. inspection system, or from another country eligible to export slaughtered poultry products to the U.S., would be permitted. However, as no processed poultry was ever exported to the U.S., FSIS suspended the PRC's eligibility based on its inability to verify on-going equivalence through its usual mechanisms, which include port-of-entry (POE) testing and on-site audits.”

—**Evaluation and response of China:** In fact, the United States had completed related legislative processes in 2006 to approve import of cooked poultry meat by processing of imported materials for export, but the disturbance of the U.S. Congress results in the U.S. can not carry out assessments on customs declaration port inspection on China's cooked poultry products and regular mechanisms including on-site review. Please amend this part of the report, making accurate presentations of the appropriation restriction act of the U.S. Congress prohibiting the import of Chinese cooked poultry meat. For example, the U.S. also gave a similar description in the inspection report of slaughtering system, as follows: Although the PRC proffered corrective actions, due to the enactment of the US Omnibus Appropriations Act (Section 733)).

## **II. GOVERNMENT OVERSIGHT (Article 5 in the Review Report)**

8. —**The report is written that** “Funding for CCA operations is provided by the central government and supplemented by fees assessed by the government on exported products.”

—**Evaluation and response of China:** The reality is that CCA operation funds are entirely from the full allocation of the central government finance with no need of charging export products to supplement the CCA funding. Please make appropriate modifications according to the facts.

9. —**The report is written that** “FSIS auditors observed that the CCA delegates to 31 inspection and quarantine bureaus (CIQ) located throughout the country the responsibility to implement inspection of animals and animal products”.

—**Evaluation and response of China:** In fact, there are 35 Inspection and Quarantine

Bureaus directly under the AQSIQ throughout the country. Please make appropriate modifications according to the facts.

10. — **The report is written that** “However, the FSIS requirement of ultimate control and supervision over inspector’s verification of sanitation activities was not consistently being met since the CCA allows establishment-paid inspectors to conduct regular pre-operational sanitation verification at processing establishments. The use of establishment-paid inspectors conducting inspection related activities can result in biased decisions leading to the export of unsafe poultry products to the U.S. This arrangement constitutes a conflict of interest, and does not meet the requirements for ultimate control and supervision over the official activities of all employees of the system articulated by the FSIS import regulations (9 CFR 381.196).”

— **Evaluation and response of China:** At present, the Chinese requirements of pre-operational check for cooked poultry meat processing establishments are that establishments shall conduct daily pre-operational sanitary check, and CIQ official also shall carry out on-site verification of the establishments’ pre-operational inspection and review related records in daily supervision. The reason why FSIS auditor come to the conclusion that CCA utilizes establishment-paid employees to conduct official duties is that they mistaked the pre-operation check by establishment as the duty carried out by CIQ during the on-site audit.

China learned the US’s daily check requirements, including what to be checked, frequency and who check. China does not allow establishment-paid personnel to perform the official regulatory functions, including pre-operational inspection and daily inspection. The U.S. aditor found that individual CIQ personnel did not understand thoroughly daily inspection, as the United States mentioned in the exit meeting that a CIQ official in a province of the five provinces had a bias understanding, but the issue of individual can not represent the whole of China; In addition, the misunderstanding of CIQ official is the monitoring frequency for cooked products processing establishments rather than the implementation body. Therefore, it is not proper for auditors to conclude that establishment-paid employees conduct official daily inspection and pre-operational examination in cooked products processing establishments.

The AQSIQ has formulated the *Inspection and Quarantine Manual for Poultry Exported to America.*, which has made detailed provision on daily inspection and pre-operational examination(See 2.3.1.1Routine supervision and management). Training will also be enhanced to avoid misunderstanding of individual inspectors.

11. — **The report is written that** “The auditors noted that, in many cases, the provincial CIQs autonomously oversee the functions of the inspection system by designing and implementing inspection-related procedures in accordance with national standards, in addition to those standards imposed by other importing countries. However, FSIS concluded that this

autonomy creates significant variation in the application of these standards amongst provinces. For example, FSIS auditors observed that the CCA does not verify in a uniform manner that poultry processing plants are controlling *Listeria monocytogenes* (Lm) in the post-lethality environment. The lack of standardized inspection procedures, and thus the lack of government oversight of its inspection personnel, is a recurring finding within the PRC's system, as further evidenced in subsequent portions of this report."

—**Evaluation and response of China:** At present, the AQSIQ has uniformly require CIQs to test *Listeria monocytogenes* in export products, and require establishments to test and control by-self both products and processing environments. But according to the regulations of the U.S., the Chinese authorities shall monitor *Listeria* in heated environment and verify enterprises' supervision. Although there are no clearly defined provisions that the CIQ shall monitor related microbias in environment, some of CIQs did carry out *Listeria* monitoring in heated environment. China believes that in accordance with the relevant requirements of China's food safety, food-borne path-microorganisms must not be detected in meat products.

The CIQs at all levels are responsible for monitoring final products, meanwhile the establishments shall test each lot of final products, and only qualified products that are pollution-free and have no pathogenic microorganisms are allowed for export. Although the CIQ has no uniform measures for verification the controlling of *Listeria* in cooked processing environment, it has resulted in the same effects as the requirements of the U.S.

Please make appropriate modifications with accurate presentation.

In order to achieve export of cooked poultry products to the United States as soon as possible, China is willing to take the U.S.'s approach to make unified provisions, and China has formulated the *Microorganism Monitoring Program for Export Poultry Products* which require uniformly to monitor microorganisms including *Listeria monocytogenes* (Lm) in both export poultry meat products and processing environment. And relevant trainings are planed.

12. —**The report is written that** "However, the FSIS auditors noted that CIQ official inspectors did not demonstrate an ability to verily that the implementation of HACCP and microbiological testing programs was consistent with government requirements. While the auditors observed that the inspection system presented provisions for training of personnel, these findings indicated that employee training was not at a level to ensure consistent performance, as previously mentioned and covered in the HACCP Systems component."

—**Evaluation and response of China:** the AQSIQ has mechanism of training inspectors of export meat products. There may be differences in abilities of individual inspectors. According to irregular flight inspection on export meat inspection and quarantine

supervision and implementation of relevant laws and regulations in different inspection and quarantine agencies, if there is a big difference in the scale and ability of law enforcement, the AQSIQ will timely organize training on inspection and quarantine supervisors. Please make appropriate modifications according to the facts.

In order to achieve export of cooked poultry products to the United States as soon as possible, China is willing to take the U.S.'s approach. The AQSIQ will further improve the mechanism of training inspection, quarantine staff and supervisors of export poultry meat products. The AQSIQ is currently developing training programs, *Training Materials of Inspection and Quarantine Supervision on Export Poultry Meat and Its Products* and strengthening pre-service training on relevant inspectors and ongoing training with rigorous assessment. Regarding microbial control, the AQSIQ has developed the *Microorganism Monitoring Program for Export Poultry Products* to make unified provisions in monitoring export poultry meat products, processing environment as well as microorganisms including Listeria by developing the *Microorganism Monitoring Program for Export Poultry Products*, and carry out relevant trainings.

### III. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (Item 6 in the Audit Report)

14. —The report is written that "The auditors noted the use of establishment-paid inspectors conducting official activities, such as pre-operational sanitation verification at processing establishments constitutes a potential conflict of interest."

—**Evaluation and response of China:** At present, the Chinese requirements of pre-operational check for cooked poultry meat processing establishments are that establishments shall conduct daily pre-operational sanitary check, and CIQ official also shall carry out on-site verification of the establishments' pre-operational inspection and review related records in daily supervision. The reason why FSIS auditor come to the conclusion that CCA utilizes establishment-paid employees to conduct official duties is that they mistaked the pre-operation check by establishment as the duty carried out by CIQ during the on-site audit.

China learned the US's daily check requirements, including what to be checked, frequency and who check. China does not allow establishment-paid personnel to perform the official regulatory functions, including pre-operational inspection and daily inspection. The U.S. aditor found that individual CIQ personnel did not understand thoroughly daily inspection, as the United States mentioned in the exit meeting that a CIQ official in a province of the five provinces had a bias understanding, but the issue of individual can not represent the whole of China; In addition, the misunderstanding of CIQ official is the monitoring frequency for cooked products processing establishments rather than the implementation body. Therefore, it

is not proper for auditors to conclude that establishment-paid employees conduct official daily inspection and pre-operational examination in cooked products processing establishments. Please make proper modification according to the facts.

#### **IV. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS** (Item 8 in the Audit Report)

15. — **The report is written that** "The auditors made multiple significant findings".

— **Evaluation and response of China:** They are not multiple significant findings, which should be modified into some findings. Please make appropriate modifications according to the facts.

16. — **The report is written that** "Failure to specifically identify Lm as a potential biological hazard likely to occur in the post-lethality processing environment in their hazard analysis. However, establishments did have sanitary controls in place controlling the post-lethality environment."

— **Evaluation and response of China:** There are only two of the six establishments audited failed to specifically identify Lm as a potential biological hazard likely to occur in the post-lethality processing environment in their hazard analysis. However, establishments did have sanitary controls in place controlling the post-lethality environment as mentioned in the U.S.'s inspection report. The problems of two establishments can not be extended to all establishments and even the whole Chinese system. Please amend the paragraph in the report that two of six establishments audited failed to specifically identify Lm as a potential biological hazard likely to occur in the post-lethality processing environment in their hazard analysis.

In order to achieve export of cooked poultry products to the United States as soon as possible, China has formulated the *Microorganism Monitoring Program for Export Poultry Products*, which refers to the relevant regulations and hazard analysis control guidelines of the U.S., and specifically requires heat processing poultry establishments and authorities (CIQ) for sampling detection on post-lethality processing environment to control Lm (See attachment 2 and 3 of the monitoring program). Please make appropriate modifications according to the facts.

China is proposed hazard analysis and control measures guidelines of cooked poultry meat, which to specifically identify Lm as a potential biological hazard likely to occur in the post-lethality processing environment in the hazard analysis.

17. — **The report is written that** “The stabilization step for heat-treated products was not identified in the hazard analysis in some establishments.”

— **Evaluation and response of China:** There are only two in the six audited establishments with this problem, which can not be extended to all establishments and even the whole China. Please modify the sentence of the paragraph into "in two establishments".

In order to achieve export of cooked poultry products to the United States as soon as possible, China has developed *Microorganism Monitoring Program for Export Poultry Products*, which refers to the relevant regulations and hazard analysis control guidelines of the U.S., and specifically requires heat processing poultry establishments and authorities (CIQ) for sampling detection on post-lethality processing environment to control Salmonella, Lm and Bacillus cereus, etc.

In addition, the CIQ has guided establishments in comprehensive hazard analysis the stabilization step for heat-treated products and provided appropriate support materials to prove potential hazards could be controlled. Please make appropriate modifications according to the facts..

18. — **The report is written that** “In one establishment, the processing steps were omitted from the product flowchart, and as a result, the missing steps were not included in the hazard analysis of the entire process. The CIQ officials did not recognize inadequacies of the HACCP plans.”

— **Evaluation and response of China:** To guide establishments in comprehensive hazard analysis on each processing product, further improve the HACCP plan and strengthen training of CIQ supervisors and supervision. Please make appropriate modifications according to the facts..

19. — **The report is written that** “The national standard outlining requirements for HACCP systems (GB/T 19538- 2004) does not require that producers include preventive measures as part of the corrective actions to deviations from critical limits.”

— **Evaluation and response of China:** the report is not accurate. The reasons are as follows:

1. The National Standard GB/T 19538-2004, equivalent to the international standard of Codex Alimentarius Commission (CAC / RCP 1-1969, REV 3 1997, AMD 1999), is adopted and promoted in many countries in the world in line with international practice.
2. The definition of 3.4 "corrective actions" is made in the National Standard GB/T19538-2004 that corrective actions must be taken in case of deviations from critical limits. According to definition of the standard and related training materials [such as training materials about *China's Export Food Hygiene Registration Management Guide* (P108, China

Foreign Economic and Trade Press 2000, ISBN 7-8004-797-0), detailed description has been made about corrective actions]. Its corrective action includes meaning of and requirements on taking preventive measures from the recurrence of deviations, which in fact has also been proposed in the U.S. 9 CFR PART 417.3.

3. The FSIS has audit the Chinese system in 2004 and 2005, including the establishment, implementation and **maintenance** of HACCP system, also Chinese standards and regulatory requirements, but nothing had mention in the final report that the national standard GB/T 19538-2004 did not meet the relevant requirements of the FSIS.

4. Most of authorities consider that the "Preventive measures" is included in the "Corrective Actions". For example, in the HACCP regulations of juice and seafood proposed by FDA, corrective actions are required to be taken in case of any deviation from critical limits, and are not specifically addressed which to take preventive measures against deviations from critical limits.

5. This evaluation is "equivalency" rather than "identical". Corrective actions are taken in most of China's training materials and specific implementation of enterprises, including "preventing a recurrence".

6. The deficiency of no-preventing recurrence measures covered by some establishments found by FSIS in the audit report is only an individual issue rather than problem of national standard itself.

In summary, China believes that the requirements of national standard GB/T19538-2004 have equivalency with the ones of the FSIS PART 417. We suggest American party cancel the relevant content from the report.

**20. —The report is written that** The significant omission concerning preventive measures within the PRC's HACCP legislation, in addition to the lack of regulatory oversight identified at establishments, constitute systemic findings that compromise the CCA's ability to implement their HACCP requirements, and ultimately ensure the consistent production of safe poultry products intended for export to the U.S.

Therefore, FSIS concluded that the PRC's inspection system does not meet the requirement for this equivalence component)

—Evaluation and response of China : All establishments approved to export poultry products to the United States are required to have adequately established, implemented and maintained a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program. Just like what have had in FISS reports of 2004 and 2005," the HACCP programs were reviewed during the on-site audits of the four establishments. Three establishments had adequately implemented the HACCP basic requirements. In some establishments, the following deficiencies were

noted..” .

#### V. MICROBIOLOGICAL TESTING PROGRAMS (Item 10 in the Audit Report)

21. —The report is written that auditors' review of this component indicated that the CCA lacked a clear understanding of FSIS's RTE policy as outlined in 9 CFR 430.1.)

—Evaluation and response of China: China has now fully understood the definition of Ready to Eat (RTE). Previously, poultry products in China are processed in accordance with the requirements of fully cooked products, heating process is strictly controlled and contamination control measures are taken in cooking and cooked areas; and microorganism is tested through sampling from final products, which can ensure that safety of the final products. This conforms to requirements of RTE products in the United States, and is also equivalent. The Please make proper modification according to the fact.

22. —The report is written that “FSIS auditors observed that the audited establishments were testing for Lm, Listeria species, or Listeria-like organisms in the product and processing environment as mandated by the PRC. However, the CIQ officials did not review the methods used by the establishments to test either the product or environmental samples”

—Evaluation and response of China: AQSIQ has formulated the *Microorganism Monitoring Program for Export Poultry Products*, which specifically required the method to monitor microorganisms including *Listeria monocytogenes* (Lm) in both export poultry meat products and processing environment., and to verify the method(See appendix 6 of the monitoring program). Please make proper modification according to the facts.

23. —The report is written that legislation AQSIQ Order No. 26: Measures for the Administration of the Inspection and Quarantine of Meat Products at Entry and Exit, 2002, discusses that a product testing positive for "harmful and noxious substances" should be barred from export. However, this legislation fails to specifically define the terms "harmful and noxious substances." FSIS requests that the CCA clarify and submit additional information demonstrating that the PRC has a zero tolerance policy for Lm and *Salmonella* spp. in RTE product)

—Evaluation and response of China: China State Quality Inspection Administration makes Order No. 26 replaced by Order No.136, and was implemented on June 1, 2011. Article 31 of the regulations has clearly specified that "inspection and quarantine agencies shall carry out sample tests based on risk analysis on for pathogenic microorganisms, agriculture and veterinary drug residue as well as environmental pollutants and other toxic or

harmful substances in exported meat products; verify and monitor quality and safety control system during production process of exported meat"; in addition, Order No.40 issued by China State Quality Inspection Administration in 2002 defines "poisonous and harmful materials", which refer to biological, physical and chemical materials which can cause harm to agriculture and animal husbandry fishery production, human health and ecological environment. According to the definition and connotation, such materials include Listeria, Salmonella and all other pathogenic microorganisms. The United States is asked to modify according to the fact.

In order to achieve export of cooked poultry products to the United States as soon as possible, China is willing to take the U.S.'s opinions and AQSIQ has formulated the *Microorganism Monitoring Program for Export Poultry Products*, which clearly require to test Listeria and salmonella, and has a zero tolerance for Lm and Salmonella in cooked poultry products(See attachment 2 of the monitoring program).

**24. —The report is written that** "The auditors observed that three of the five provincial CIQ's audited were not conducting environmental testing to ensure that the establishments' control measures were effective in controlling Lm in the post-lethality processing environment"

**—Evaluation and response of China:** AQSIQ has formulated the *Microorganism Monitoring Program for Export Poultry Products* which should be performed by each Inspection and Quarantine Bureau. The monitoring plan includes verification of Listeria monitoring in the post-lethality processing environment, to verify effectiveness of control measures taken by establishments(See attachment 2 of the monitoring program).

**25. —The report is written that** "The FSIS auditors verified that the PRC's microbiological testing laboratories are ISO 17025 accredited and are well equipped to provide technical support to the poultry inspection system, and that laboratory management is familiar with the FSIS testing requirements. The current analytical test portions for both Lm and Salmonella spp. is 25g. FSIS requires a minimum of 25g and 325g analytical test portion for Lm and Salmonella spp."

**—Evaluation and response of China:** at present, The Chinese standard requires that Salmonella must not be detected in 25g of the poultry meat(GB2726-2005), this could guarantee the poultry meat safety and sanitary. For the testing requirements of import of the poultry meat, The Chinese Party also has the 25g sample. We have detected the pathogenic microorganisms many times in the import of poultry meat including Salmonella. And also includes the poultry meat import from the US. Please make proper modification according to the facts.

In order to promote the export of poultry meat, our Chinese Party is willing to take action as America. AQSIQ has formulated the *Microorganism Monitoring Program for Exported Poultry Products*, which requires 325g will be the minimum quantity for detecting the Salmonella in the exported cooked poultry products(See attachment 2 of the monitoring program).

26. —**The report is written that** “The lack of clear guidance concerning the definition of RTE product, and the inconsistent application of environmental testing programs greatly compromises the CCA's ability to implement an effective microbiological testing program. Consequently, the PRC's inspection system was unable to demonstrate the same level of protection as that provided by the U.S. system to control pathogenic microorganisms typically associated with processed poultry products. Therefore, FSIS concluded that the PRC's inspection system does not meet the requirement for this equivalence component.”

—**Evaluation and response of China:** China has now fully understood the definition of Ready to Eat (RTE). Previously, poultry products in China are processed in accordance with the requirements of fully cooked products, heating process is strictly controlled and contamination control measures are taken in cooking and cooked areas; and microorganism is tested through sampling from final products, which can ensure that safety of the final products. This conforms to requirements of RTE products in the United States, and is also equivalent. In order to achieve export of cooked poultry products to the United States as soon as possible, China is willing to take the U.S.'s definition of RTE, which specified the definition of RTE in *Inspection and Quarantine Manual for Poultry Exported to America*. Please amend it according to the facts.

There is microorganism control system in China; the America Party has approved the Chinese the inspection and verification of microorganism system during the reviewing of questionair. We executed the microorganism inspection system that lay special focus on the inspection of finished products and the process of verification at the same time in China, meanwhile America attaches importance on the process of verification. This is only inconsistent with each other on the control methods. The microorganism control system in China could guarantee the safety of products, which is completely reach the protection standards of American, the American shall not deny the Chinese verification and control system because it is not inconsistent with American on the control methods. To implement the exit of poultry products to America, The Chinese Party is willing to adopt the American methods of microorganism control, and has already formulated the *Microorganism Monitoring Program for Export Poultry Products*

**VI. CONCLUSIONS AND NEED FOR FURTHER ACTIONS) (Item 12 in the Audit Report)**

27. —The report is written that “FSIS concluded that the CCA was able to meet the principal requirements for the Sanitation equivalence component. The assessment of actual establishment conditions in association with inspection records and interviews with AQSIQ officials indicated that these individuals were proficient in conducting verification and enforcement activities related to sanitation. However the requirements for internal audits conducted bi-annually by establishments in accordance with Section 8, Article 16 of AQSIQ Directive No. 20 were not clearly defined, thereby representing a need for further written guidance from the CCA to ensure that the implementation and verification of this national standard occurs as intended.”

—**Evaluation and response of China:** The Section 16, Article 2 of AQSIQ Order No. 20 promulgated by AQSIQ stipulated that supervise and control on the effectiveness of the sanitary and quality management system of establishments, at the same time, Section 17, Article 2 stipulated that the establishments which obtained the foreign sanitation registered certificate shall be inspected comprehensively every half year (or according to the production season). The above content covers the inspection requirements on the internal approval on the institute. On the basis of the above functions, the Chinese Party has made out the written training materials for the internal auditor and official sanitary registration auditor, in which specify the process and requirements for the inspection on the internal audition in companies. Please amend it according to the facts.

28. —The CCA provides limited coordination of its inspection staff as it pertains to the issuance of written training materials and inspection manuals, relying extensively on the provincial Inspection and Quarantine Authorities (CIQ) to develop this guidance. However, the auditors noted that this autonomy resulted in significant variation in the application of national and export poultry standards amongst provinces.

—**Evaluation and response of China:** AQSIQ has promulgated the *Inspection and Quarantine Manual for Poultry Exported to Americ* which is implemented by the CIQs. We believe that it is some kind of different between each CIQ on the specific actions, but no big differences. The present action can also guarantee the safety of the products. Please amend it according to the facts.

In order to achieve export of cooked poultry products to the United States as soon as possible, the AQSIQ has formulated the *Inspection and Quarantine Manual for Poultry Exported to Americ*, which makes unified requirements on inspection procedures and supervisors in export

of cooked poultry meat products to the U.S.; and has formulated the *Microorganism Monitoring Program for Export Poultry Products*, which makes unified provisions in monitoring both export poultry meat products and processing environment, and will carry out related trainings on the inspection and quarantine regulators of export meat products.

29. —The CCA does not uniformly verify that poultry processing plants control *Listeria monocytogenes* (Lm) in the post-lethality environment.

—**Evaluation and response of China:** CCA has uniformly require CIQs to test *Listeria monocytogenes* in export products, and require establishments to test and control by-self both products and processing environments. But according to the regulations of the U.S., the Chinese authorities shall monitor *Listeria* in heated environment and verify enterprises' supervision. Although there are no clearly defined provisions that the CIQ shall monitor related microorganisms in environment, some of CIQs did carry out *Listeria* monitoring in heated environment. China believes that in accordance with the relevant requirements of China's food safety, food-born path-microorganisms must not be detected in meat products. The CIQs at all levels are responsible for monitoring final products, meanwhile the establishments shall test each lot of final products, and only qualified products that are not contaminated and have no pathogenic microorganisms are allowed for export. Although the CIQ has no uniform measures for verification the controlling of *Listeria* in cooked processing environment, it has resulted in the same effects as the requirements of the U.S. Please make appropriate modifications with accurate presentation.

In order to achieve export of cooked poultry products to the United States as soon as possible, China is willing to take the U.S.'s approach to make unified provisions, and China has also formulated the *Microorganism Monitoring Program for Export Poultry Products*, which require uniformly to monitor microorganisms including *Listeria monocytogenes* (Lm) in both export poultry meat products and processing environment(See attachment 2 of the Monitoring plan). And relevant trainings are planed.

30. —**The report is written that “The report is written that** The national standard outlining requirements for HACCP systems (GB/T 19538- 2004) does not require that producers include preventive measures as part of the corrective actions to deviations from critical limits.”

—**Evaluation and response of China:** the report is not accurate. The reasons are as follows:

1.The National Standard GB/T 19538-2004, equivalent to the international standard of Codex

Alimentarius Commission (CAC / RCP 1-1969, REV 3 1997, AMD 1999), is adopted and promoted in many countries in the world in line with international practice.

2. The definition of 3.4 "corrective actions" is made in the National Standard GB/T19538-2004 that corrective actions must be taken in case of deviations from critical limits. According to definition of the standard and related training materials [such as training materials about *China's Export Food Hygiene Registration Management Guide* (P108, China Foreign Economic and Trade Press 2000, ISBN 7-8004-797-0), detailed description has been made about corrective actions]. Its corrective action includes meaning of and requirements on taking preventive measures from the recurrence of deviations, which in fact has also been proposed in the U.S. 9 CFR PART 417.3.

3. The FSIS has audit the Chinese system in 2004 and 2005, including the establishment, implementation and **maintenance** of HACCP system, also Chinese standards and regulatory requirements, but nothing had mention in the final report that the national standard GB/T 19538-2004 did not meet the relevant requirements of the FSIS.

4. Most of authorities consider that the "Preventive measures" is included in the "Corrective Actions". For example, in the HACCP regulations of juice and seafood proposed by FDA, corrective actions are required to be taken in case of any deviation from critical limits, and are not **specifically addressed** which to take preventive measures against deviations from critical limits.

5. This evaluation is "equivalency" rather than "identical". Corrective actions are taken in most of China's training materials and specific implementation of enterprises, including "preventing a recurrence".

6. The deficiency of no-preventing recurrence measures covered by some establishments found by FSIS in the audit report is only an individual issue rather than problem of national standard itself.

In summary, China believes that the requirements of national standard GB/T19538-2004 have equivalency with the ones of the FSIS PART 417.

**31. —The report is written that "The report is written that** Regulatory verification of HACCP systems employed by poultry processing plants is not adequate, demonstrated by establishments having How charts that are inadequately designed and failing to identify biological hazards."

—**Evaluation and response of China:** China is proposed hazard analysis and control measures guidelines of cooked poultry meat, which specifically identify Lm as a potential biological hazard likely to occur in the post-lethality processing environment in the hazard analysis. It will guide establishments to conduct a comprehensive hazard analysis on each processed products to further improve the HACCP plan and strengthen training and supervision on the CIQ supervisors. Please amend it according to the facts

32. —The report is written that “The report is written that The CCA utilizes establishment-paid employees to conduct official inspection duties, such as pre-operational sanitation verification, which constitutes a potential conflict of interest”

—**Evaluation and response of China:** At present, the Chinese requirements of pre-operational check for cooked poultry meat processing establishments are that establishments shall conduct daily pre-operational sanitary check, and CIQ official also shall carry out on-site verification of the establishments’ pre-operational inspection and review related records in daily supervision. The reason why FSIS auditor come to the conclusion that CCA utilizes establishment-paid employees to conduct official duties is that they mistaked the pre-operation check by establishment as the duty carried out by CIQ during the on-site audit.

China learned the US’s daily check requirements, including what to be checked, frequency and who check. China does not allow establishment-paid personnel to perform the official regulatory functions, including pre-operational inspection and daily inspection. The U.S. aditor found that individual CIQ personnel did not understand thoroughly daily inspection, as the United States mentioned in the exit meeting that a CIQ official in a province of the five provinces had a bias understanding, but the issue of individual can not represent the whole of China; In addition, the misunderstanding of CIQ official is the monitoring frequency for cooked products processing establishments rather than the implementation body. Therefore, it is not proper for auditors to conclude that establishment-paid employees conduct official daily inspection and pre-operational examination in cooked products processing establishments. Please make proper modification according to the facts.

**Attachment 2:**

## Comments on the U.S.'s Audit Report on Chinese Poultry Slaughter Control System

### I. Executive Summary

1. —The report is written that “The CCA provides only limited coordination of its inspection staff as it pertains to the issuance of written training materials and inspection manuals, relying extensively on the provincial CIQ to develop this guidance. Consequently, the auditors noted that this autonomy resulted in significant variation in the application of national standards amongst provinces. “

**Reply from PRC:** The AQSIQ develops the *Instructions on Inspection and Quarantine of Exported Poultry* which is implemented specifically by provincial CIQ. China side think although slight difference exists in the application of national standards among provincial CIQs, there is no significant variation so that the current practice can guarantee quality and safety of products.

In order to achieve the export of cooked poultry products to U.S., AQSIQ has developed two documents, one is the *Inspection and Quarantine Manual for Poultry Exported to America* which stipulates uniform requirements and procedure of inspection as well as the quality, capability and training programs of the staff responsible for cooked poultry products export to U.S. and the other is the *Microorganism Monitoring Program for Exported Poultry Products* which stipulates uniform requirements for microbial monitoring of export poultry products and processing environment.

2. —The report is written that “The CCA lacks a standardized method to assign inspection personnel to slaughter facilities based on objective measurements such as production line rates, inspection workloads, or line configuration.”

**Reply from PRC:** At present, AQSIQ delegates local CIQs to inspect and supervise the slaughter facilities. The local CIQs is responsible to assign inspection personnel based on the production capacity of the slaughter facilities. Although the inspector is not assigned according to the method of US, the assignment is still reasonable.

PRC has learned the method of U.S. to assign inspection personnel based on production line rates, inspection workloads, production line quantity and line configuration in slaughter facilities, and has developed the *Inspection and Quarantine Manual for Poultry Exported to America* to clarify how to assign inspection personnel in slaughterhouse(See III. Allocation of official inspection quarantine inspectors in appendix 1 of the maunal).

3. —The report is written that “The CCA utilizes establishment-paid inspectors to conduct official inspection duties. This is a repeat finding from the 2005 FSIS audit. “

**Reply from PRC:** At present, under the supervision of official veterinarians, the ante-mortem and post-mortem inspections of export poultry in PRC are carried out jointly by CIQ-paid inspectors and establishment-paid inspectors who are approved by CIQ. In PRC, ante-mortem and post-mortem activities are conducted under the supervision of official veterinarians so that we can guarantee quality and safety of raw poultry products. At present, poultry processing and slaughter system of PRC has been approved by many countries who import poultry products from PRC. Cooked poultry products can be export to EU, Japan and other countries, and the trade goes smoothly.

In order to achieve the export of poultry products to U.S. as soon as possible, PRC is willing to adopt equivalent requirements for ante-mortem and post-mortem inspections of U.S. In the event of export of poultry products to U.S., PRC will comply with its inspection system to assign CIQ-paid inspectors to conduct ante-mortem and post-mortem inspections in processing enterprises that export poultry products to U.S.

4. —The report is written that “Post-mortem activities conducted by CIQ veterinarians and establishment-paid inspectors did not ensure consistent identification of pathological conditions.”

**Reply from PRC:** AQSIQ develops the training programs for inspectors responsible for control of export meat products. During actual inspections, there may exist difference of capability among some inspectors. AQSIQ makes irregular flight inspections (inspection without advance notice) on the inspection and supervision situation of export meat products and the implementation situation of relevant regulations by local CIQs. If AQSIQ finds the variation of law enforcement and the difference of capability among inspectors, AQSIQ will provide training to inspectors promptly.

In order to achieve the export of poultry products to U.S., AQSIQ will further improve the training mechanism for inspection and supervision personnel of export poultry products. At present, AQSIQ is developing the training plan, defining the training manner, confirming the training class hours, revising the *Training Program in Supervision, Inspection and Quarantine for Exported Poultry and Related Products*, strengthening training of relevant inspectors before working, providing continuous trainings and making strict assessment. For microbial monitoring, AQSIQ has developed the *Microorganism Monitoring Program for Exported*

*Poultry Products* to makes uniform requirements for microbial monitoring of export poultry products and processing environment and will provide relevant trainings.

**5. —The report is written that** “The CCA was not fully aware of FSIS’ requirements for ready-to-cook poultry outlined in 9 CFR 381.1”

**Reply from PRC:** In fact, CIQ is fully aware of FSIS’ requirements for ready-to-cook poultry outlined in 9 CFR 381.1. When FSIS made investigation on the export poultry system of PRC in 2004, CCA and FSIS made communication about the issue of ready-to-cook poultry. FSIS acknowledged that it was not required for PRC to process ready-to-cook poultry not exported to U.S. in compliance with relevant requirements of U.S. After 2004, CCA provides inspectors with much training of relevant regulations about poultry inspection of U.S. and is fully aware of requirements for ready-to-cook poultry in U.S. The reason that causes the misunderstanding is the lack of communication or the translation.

In the event of export to U.S., PRC will comply with requirements of American regulations to remove head and oil glands from carcass before pre-chilling in case of producing read-to-cook poultry exported to U.S. *Inspection and Quarantine Manual for Poultry Exported to America*. developed by AQSIQ defines the issue in details(See 2.3.2.4 and appendix 6 of the Manual).

**6—The report is written that** “The national HACCP standard, GB/T19538-2004, does not require food producers to establish measures to prevent recurrence in response to a deviation from the critical limit. This does not meet FSIS’ equivalence criteria applied to foreign HACCP systems, which are based on the requirements found in 9 CFR 417.”

**Reply from PRC:** The report of U.S. is inaccurate. Reasons are defined as follows:

(1) National standard GB/T 19538-2004, equivalent to CAC/RCP 1-1969, REV 3 1997, AMD 1999, conforms to international practice; it is applied and popularized in many countries in the world.

(2) Corrective actions outlined in Clause 3.4 of GB/T 19538-2004 defines that it is required to adopt corrective actions in the event of deviation from the critical limit. According to the definition of standard and the relevant training material [e.g.: the *Guide on Administration of Registering Chinese Exported Food* details such corrective actions (P108, China Foreign Economic Relations & Trade Publishing House, 2000, ISBN 7-8004-797-0)], CA contains the meaning and requirement for adopting measures to prevent recurrence. In fact, 9 CFR PART 417.3 also make the requirement to establish corrective actions.

(3) FSIS inspected relevant systems of PRC in 2004 and 2005, including the establishment, implementation and maintenance of HACCP system and the requirements of Chinese standards and regulations. However, FSIS did not clarify that GB/T 19538-2004 did not

comply with relevant requirements of FSIS in the final report.

(4) Most of authorities consider that the "Preventive measures" is included in the "Corrective Actions". For example, in the HACCP regulations of juice and seafood proposed by FDA, corrective actions are required to be taken in case of any deviation from critical limits, and are not specifically addressed which to take preventive measures against deviations from critical limits.

(5) This audit is to assess the equivalence instead of identity; in training materials of PRC and specific implementation of enterprises, corrective actions are adopted mostly, including measure to prevent recurrence.

(6) During the investigation of U.S., it is just an individual case that certain enterprises do not establish the procedure of Prevent recurrence, but it does not mean that the standard has any problem.

In conclusion, CCA think that GB/T 19538-2004 is equivalent to FSIS Part 417. CCA .

**7—The report is written that** "The CCA did not consistently enforce HACCP verification requirements or take appropriate action when establishment Critical Control Point (CCP) monitoring did not identify deviations when they occurred."

**Reply from PRC:** Pursuant to these Audit Reports of U.S. in PRC, enterprises establish and implement HACCP system in accordance with relevant requirements and basically comply with requirements, but some specific problems still exist in enterprises. Some enterprises establish, implement and maintain HACCP inadequately, and some CIQ officials make poor management of CCP monitoring. These problems are caused by incapable inspectors. Nevertheless, relevant HACCP regulations and standards of PRC are basically equivalent to FSIS regulations. In addition, measures of mandatory enforcement are identical.

Next, AQSIQ will improve the training mechanism for inspection and supervision personnel of export poultry products, such as developing the training plan, defining the training manner, confirming the training class hours, establishing the *Inspection and Quarantine Manual for Poultry Exported to America*, strengthening training of relevant inspectors before working, providing continuous trainings making strict assessment, enhancing capability of inspectors and guaranteeing the effect of supervision and inspection on enterprises.

**8. —The report is written that** "The CCA could not demonstrate uniform application of its microbial testing requirements for raw poultry. During the exit meeting, the CCA committed to implementing FSIS' requirements outlined in 9 CFR 381.94. In order to honor this commitment, the CCA is to demonstrate that it has taken the appropriate measures to ensure uniform application of these requirements as it pertains to sample collection and

frequency, analysis of samples, recording and evaluation of test results, adherence to performance standards, and enforcement throughout its inspection system. The documentation provided should indicate the CCA's ability to implement the revised performance standards for raw poultry in accordance with the March 21, 2011 Federal Register Notice, and associated WTO notification on March 23, 2011 (notification number SPS/N/USA/2029).”

**Reply from PRC:** In fact, samples collection techniques of CCA all comply with requirements of GB16869-2005. Sampling site and techniques of microbial samples are consistent with FSIS regulations and enforced to implement in the nation. CCA develops uniform control system of raw poultry microbial testing, which is already approved by FSIS in the examination of questionair so the safety of exported products can be guaranteed.

Since 2004, CCA has started to translate 9 CFR 381, make relevant training, and apply new requirements pursuant to the change of U.S. regulations. During the inspection in some enterprises, FSIS already saw the official demonstration of chicken sampling method for E-coli and salmonella. It indicates that inspectors of PRC are aware of requirements of U.S. towards colibacillus and salmonella in slaughter facilities.

In order to achieve the export of poultry products to U.S., AQSIQ is willing to adopt the method of U.S., comply with requirements outlined in 9CFR381.9 by FSIS, develop the *Microorganism Monitoring Program for Exported Poultry Products*, make uniform requirements of export poultry products and processing environment (i.e. product sampling locations, sample collection techniques, recording and evaluation of test results, and adherence to performance standards), and provide relevant training.

## **II. Audit objective, Scope and Method**

9. Local offices locations of CIQ in the Audit Scope Summary are Zhucheng and Qingdao.

**Reply from PRC:** The information is incorrect. Correct local offices locations of CIQ are Zhucheng and Weifang.

10. Government laboratory location of CIQ in the Audit Scope Summary is Technical Center of Inspection and Quarantine No.70, Qingdao, Shandong.

**Reply from PRC:** The information is incorrect. Correct government laboratory location is the Inspection & Quarantine Technical Center of Shandong Entry-Exit Inspection And Quarantine Bureau.

## **III. Background (Item 4 in the Audit Report)**

11. The PRC first requested an initial equivalence determination of its poultry slaughter inspection system in May 2004, for which FSIS conducted on-site audits in 2004 and 2005.

During the 2005 audit, significant issues were identified concerning the payment of official inspectors, and the use of certain residue analytical methods. Although the PRC proffered corrective actions, due to the enactment of the U.S. Omnibus Appropriations Act (Section 733), the equivalence process was never completed, and the corrective actions were not verified. In the interim, The Food Safety Law (FSL) of the PRC (2009) was enacted, requiring FSIS to evaluate the impact this new legislation had on the CCA's authority to provide oversight to its poultry inspection system. As a result, in June 2010, FSIS sent a team to PRC to collect all applicable legislation affecting the poultry slaughter inspection system.

**Reply from PRC:** In 2004 and 2005, delegation of U.S. made two on-site investigations of slaughter inspection system in PRC. U.S. also express many times that the inspection system of PRC is equivalent to that of U.S. and the legislative process has been initiated. **The enactment of the U.S. Omnibus Appropriations Act by the US Congress results in suspension of cooked product legislative process in PRC.** However, the enactment of the Food Safety Law (FSL) of the PRC (2009) means that PRC strengthens the official control of food safety. It cannot be the reason that U.S. reevaluates the poultry slaughter system of PRC.

#### **IV. Government oversight (Item 5 in the Audit Report)**

**12. Funding for CCA operations is provided by the central government and supplemented by fees assessed by the government on export products.**

**Reply from PRC:** In fact, funding for CCA operations is provided by the central government, and it is not necessary to charge fees assessed by the government on export products for the purpose of supplementing the funding for CAA.

**13. FSIS auditors observed that the CCA delegates to the 31 inspection and quarantine bureaus (CIQ) located through the country.**

**Reply from PRC:** The information is incorrect. Correct information is that the CCA delegates to the 35 inspection and quarantine bureaus (CIQs) located through the country.

**14. However, similar to what was observed during the 2005 audit, the FSIS auditors noted that antemortem and postmortem inspection duties were conducted by both CIQ contracted veterinarians and establishment-paid inspectors..... While the PRC was not yet fully operating in U.S.-mode during the audit, the FSIS auditors nonetheless concluded that this arrangement constitutes a conflict of interest, and does not meet the requirements for having ultimate control and supervision over the official activities of all employees or having ultimate control and supervision over the official activities of all employees or licensees of the system, as articulated in the FSIS import regulations (9 CFR 381.196).**

**Reply from PRC:** At present, under the supervision of official veterinarians, the ante-mortem and post-mortem inspections of export poultry in PRC are carried out jointly by CIQ-paid inspectors and establishment-paid inspectors who are approved by CIQ. In PRC, ante-mortem and post-mortem activities are conducted under the supervision of official veterinarians so that we can guarantee quality and safety of raw poultry products. At present, poultry processing and slaughter system of PRC has been approved by many countries who import poultry products from PRC. Cooked poultry products can be export to EU, Japan and other countries. It is very successful to export poultry products.

In order to achieve the export of poultry products to U.S. as soon as possible, PRC is willing to adopt equivalent requirements for pre-mortem and post-mortem inspections of U.S. In the event of export of poultry products to U.S., PRC will comply with its inspection system to assign CIQ-paid inspectors to conduct pre-mortem and post-mortem inspections in processing enterprises that export poultry products to U.S.

**15. The auditors noted that, in many cases, the provincial CIQs autonomously oversee the functions of the inspection system by designing and implementing in section-related procedures in accordance with national standards, in addition to those standards imposed by other importing countries. However, FSIS concluded that this autonomy creates significant variation in the application of these standards amongst provinces. For example, FSIS auditors observed that sample collection procedures associated with testing for Salmonella spp. in raw products, on -line presentation of carcasses, and official inspection of viscera were not performed consistently throughout the selected establishments. The lack of standardized inspection procedures is a recurring finding within the PRC's system, as further evidenced in subsequent portions of this report.**

**Reply from PRC:** The AQSIQ develops the *Instructions on Inspection and Quarantine of Exported Poultry* which is implemented specifically by provincial CIQs. In addition, national mandatory standards, such as GB16869-2005, are required to make uniform enforcement in the nation. According to relevant provisions of AQSIQ, Bureau of Import and Export Food Safety supervise the law enforcement of local CIQs, and provincial CIQs also supervise the inspection situation of CIQ branches to guarantee the unity of law enforcement by local CIQs. Although slight difference exists in the application of national standards among provincial CIQs, there is no significant variation so that the current practice can guarantee quality and safety of products. In the on-site inspection, FSIS found that sampling location and method are different. The reason is that FSIS regards the demonstrative sampling of colibacillus and salmonella on the site pursuant to 9 CFR381.94 as daily sampling. However, significant

variation does not always occur when local CIQs implement standards such as GB16869-2005.

In order to achieve the export of cooked poultry products to U.S., AQSIQ has developed the *Inspection and Quarantine Manual for Poultry Exported to America* which makes uniform requirements for inspection procedure and staff of cooked poultry products export to U.S. and the *Microorganism Monitoring Program for Exported Poultry Products* which makes uniform requirements for microbial monitoring of export poultry products and processing environment, and will provide relevant trainings to the inspection staff of export meat products.

**16. However, the FSIS auditors noted that CIQ official inspectors did not demonstrate an ability to oversee the implementation of HACCP and microbiological testing programs. Furthermore, the CIQ contracted veterinarian and the establishment-paid inspectors conducting postmortem inspection did not recognize some pathological lesions. While the auditors observed that the inspection system has provisions for training of personnel, these findings indicated that employee training was not adequate to ensure consistent performance of food safety related oversight activities.**

**Reply from PRC:** AQSIQ develops the training system for inspectors of export meat products. During actual inspections, there may exist difference of capability among some inspectors. AQSIQ makes irregular flight inspections on the inspection and supervision situation of export meat products and the implementation situation of relevant regulations by local CIQs. If AQSIQ finds the variation of law enforcement and the difference of capability among inspectors, AQSIQ will provide training to inspectors promptly.

In order to achieve the export of poultry products to U.S., AQSIQ will further improve the training mechanism for inspection and supervision personnel of export poultry products. At present, AQSIQ is developing the training plan, defining the training manner, confirming the training class hours, revising the *Training Program of Supervision, Inspection and Quarantine for Exported Poultry and Related Products*, strengthening training of relevant inspectors before working, providing continuous trainings and make strict assessment. For microbial monitoring, AQSIQ has developed the *Microorganism Monitoring Program for Export Poultry Products* to makes uniform requirements for microbial monitoring of export poultry products and processing environment and will provide relevant trainings.

**17. The autitors' review of staffing protocols indicated that the CCA lacks a standardized method to assign inspection personnel to slaughter facilities based on**

**objective measurements such as production line rates, inspection workloads, or line configuration. This indicates an inability for the CCA to assign inspection personnel to certified facilities in a uniform manner, or ensure a sufficient level of inspection staffing when changes in volume and rate of production occur at individual establishments.**

**Reply from PRC:** At present, AQSIQ requires local CIQs to make inspection and supervision of slaughter facilities. These CIQs assign inspection personnel to slaughter facilities pursuant to production capacity of slaughter facilities. Although we do not make calculation based on the said measurements of U.S., we can assign inspection personnel reasonably.

PRC has learned the method of U.S. to assign inspection personnel based on production line rates, inspection workloads, production line quantity and line configuration in slaughter facilities, and has developed the *Inspection and Quarantine Manual for Poultry Exported to America* to clarify how to assign inspection personnel in processing enterprises (See III. Allocation of official inspection quarantine inspectors of Appendix 1 in the Manual).

**18. The systemic findings associated with this component indicate an inability for the CCA to apply these standards uniformly at poultry slaughter establishments, compromising the CCA's ability to ensure the consistent production of safe poultry products intended for export to the U.S. Furthermore, the use of establishment-paid inspectors making official dispositions on poultry carcasses may result in biased decisions leading to the export of unsafe poultry products to the U.S. This also fails to meet the core requirements for an equivalent inspection system outlined in 9 CFR 381.196. Therefore, FSIS concluded that the PRC's inspection system does not currently meet the requirement for this equivalence component.**

**Reply from PRC:** (1) In fact, AQSIQ is capable to ensures that local CIQs are able to apply these relevant requirements (including national mandatory standards) uniformly at poultry slaughter establishments, and relevant measurements are already clarified in the said issues. That is, the AQSIQ develops the *Instructions on Inspection and Quarantine of Exported Poultry* which is implemented specifically by provincial CIQs. In addition, national mandatory standards, such as GB16869-2005, are required to make uniform enforcement in the nation. According to relevant supervision provisions of AQSIQ, Bureau of Import and Export Food Safety supervise the law enforcement of local CIQs, and provincial CIQs also supervise the inspection situation of CIQ branches to guarantee the unity of law enforcement by local CIQs. Although slight difference exists in the application of national standards among provincial CIQs, there is no significant variation so that the current practice can guarantee quality and safety of products. In the on-site inspection, FSIS found that sampling location and method are different. The reason is that FSIS regards the demonstrative sampling

of colibacillus and salmonella on the site pursuant to 9 CFR381.94 as daily sampling. However, significant variation does not always occur when local CIQs implement standards such as GB16869-2005.

In order to achieve the export of cooked poultry products to U.S. as soon as possible, AQSIQ will improve the training mechanism for inspection and supervision personnel of export poultry products, such as developing the training plan, defining the training manner, confirming the training class hours; AQSIQ has developed the *Inspection and Quarantine Manual for Poultry Exported to America* which makes uniform requirements for inspection procedure and inspectors of cooked poultry products export to U.S. and the *Microorganism Monitoring Program for Exported Poultry Products* which makes uniform requirements for microbial monitoring of export poultry products and processing environment, and will provide relevant trainings to the inspection staff of export meat products.

(2) At present, under the supervision of official veterinarians, the ante-mortem and post-mortem inspections of export poultry in PRC are carried out jointly by CIQ-paid inspectors and establishment-paid inspectors who are approved by CIQ. In PRC, pre-mortem and post-mortem activities are conducted under the supervision of official veterinarians so that we can guarantee quality and safety of raw poultry products. At present, poultry processing and slaughter system of PRC has been approved by many countries who import poultry products from PRC. Cooked poultry products can be export to EU, Japan and other countries. It is very successful to export poultry products.

In order to achieve the export of poultry products to U.S. as soon as possible, PRC is willing to adopt equivalent requirements for ante-mortem and post-mortem inspections of U.S. In the event of export of poultry products to U.S., PRC will comply with its inspection system to assign CIQ-paid inspectors to conduct ante-mortem and post-mortem inspections in enterprises that export poultry products to U.S. The Ministry of Agriculture enacted the *Administrative Rules on Quarantine of Animal* (Decree No. 6) on Jan. 21 of 2010, and the *Rules on Quarantine of Slaughtered Poultry* on April 12 to explicitly stipulate that official veterinarians shall conduct the ante-mortem and post-mortem inspections. At present, it is to be implemented.

## **V. Statutory Authority and Food Safety Regulations (Item 6 in the Audit Report)**

19. However, FSIS auditors observed that, in two of the three establishments visited, CIQ contracted veterinarians and establishment-paid inspectors failed to identify pathological

lesions associated with inflammatory process (cellulitis), and the affected carcasses were chilled and processed without the removal of these lesions. Furthermore, the auditors observed that there was a significant degree of variation in both inspection methodology and the manner in the presentation of carcasses for postmortem inspection. Similarly, while the GB standards for postmortem inspection clearly identify the pathological conditions necessitating removal, they do not include an underpinning inspection methodology. This was also documented in the previous audit findings related to inspector training, and the observation that the responsibility assigned to individual provinces for developing inspection procedures resulted in inconsistent application of the national standards. An analysis of these findings, as they relate to postmortem inspection, indicate a need for the CCA to further develop the competencies of its inspection personnel, as well as the standardization of inspection procedures.

**Reply from PRC:** : In fact, the standard of PRC (GB/T20094-2006) clarifies the pathological conditions need to be removed during the postmortem inspection; the *Rule for Inspection of Frozen Chicken for Export* (SN/T0419-1995) and the *Rule for Inspection of Frozen Ducks and Frozen Geese for Export* (SN/T0428-1995) define the inspection method of pathological conditions. In actual inspection, certain incapable inspectors cannot fully identify carcasses with pathological lesions, but there is no significant variation on inspection manner and method.

In order to achieve the export of cooked poultry products to U.S. as soon as possible, AQSIQ will improve the training mechanism for inspection and supervision personnel of export poultry products, such as developing the training plan, defining the training manner, confirming the training class hours, establishing the *Inspection and Quarantine Manual for Poultry Exported to America*, strengthening training of relevant inspectors before working, providing continuous trainings, making strict assessment, and enhancing capability of inspectors.

20. While observing the packaging of poultry carcasses, auditors noted that oil glands and heads were not removed from carcasses prior to shipment. This practice is permissible within the PRC, and therefore presents an equivalence concern in that FSIS' standards for ready-to-cook poultry call for removal of these portions of the bird. ....Interviews conducted with inspection personnel indicated that they were not fully aware of FSIS' requirements for ready-to-cook poultry outlined in 9 CFR 381.1.

**Reply from PRC:** : In fact, CIQ is fully aware of FSIS' requirements for ready-to-cook

poultry outlined in 9 CFR 381.1. When FSIS made investigation on the export poultry system of PRC in 2004, CCA and FSIS made communication about the issue of ready-to-cook poultry. FSIS acknowledged that it was not required for PRC to process ready-to-cook poultry not exported to U.S. in compliance with relevant requirements of U.S. After 2004, CCA provides inspectors with much training of relevant regulations about poultry inspection of U.S. and is fully aware of requirements for ready-to-cook poultry in U.S. The reason that causes the misunderstanding is the lack of communication or the translation.

In the event of export to U.S., PRC will comply with requirements of American regulations to remove heads and oil glands from carcass before precooling in case of producing read-to-cook poultry exported to U.S. *Inspection and Quarantine Manual for Poultry Exported to America* developed by AQSIQ defines the issue in details.

21. While the PRC provides a statutory framework outlining the requirements of its poultry inspection system, the current audit resulted in several systemic findings that compromise the ability of the CCA to ensure the production of wholesome poultry products intended for export to the U.S. on a consistent basis. Specifically, postmortem activities conducted by CIQ contracted veterinarians and establishment-paid inspectors did not ensure consistent identification of pathological conditions, and the CCA was not fully aware of FSIS' requirements for ready-to-cook poultry. Therefore, FSIS concluded that the PRC's inspection system does not meet the requirement for this equivalence component.

**Reply from PRC:** (1) In fact, the standard of PRC (GB/T20094-2006) clarifies the pathological conditions need to be removed during the postmortem inspection; the *Rule for Inspection of Frozen Chicken for Export* (SN/T0419-1995) and the *Rule for Inspection of Frozen Ducks and Frozen Geese for Export* (SN/T0428-1995) define the inspection method of pathological conditions. In actual inspection, certain incapable inspectors cannot fully identify carcasses with pathological lesions, but there is no significant variation on inspection manner and method.

In order to achieve the export of cooked poultry products to U.S. as soon as possible, AQSIQ will improve the training mechanism for inspection and supervision personnel of export poultry products, such as developing the training plan, defining the training manner, confirming the training class hours, establishing the *Inspection and Quarantine Manual for Poultry Exported to America*, strengthening training of relevant inspectors before working, providing continuous trainings, making strict assessment, and enhancing capability of inspectors.

(2) In fact, CIQ is fully aware of FSIS' requirements for ready-to-cook poultry outlined in 9 CFR 381.1. When FSIS made investigation on the export poultry system of PRC in 2004, CCA and FSIS made communication about the issue of ready-to-cook poultry. FSIS acknowledged that it was not required for PRC to process ready-to-cook poultry not exported to U.S. in compliance with relevant requirements of U.S. After 2004, CCA provides inspectors with much training of relevant regulations about poultry inspection of U.S. and is fully aware of requirements for ready-to-cook poultry in U.S. The reason that causes the misunderstanding is the lack of communication or the translation.

In the event of export to U.S., PRC will comply with requirements of American regulations to remove heads and oil glands from carcass before precooling in case of producing ready-to-cook poultry exported to U.S. *Inspection and Quarantine Manual for Poultry Exported to America*, developed by AQSIQ defines the issue in details.

(3) In fact, AQSIQ is capable to ensure that local CIQs are able to apply these relevant requirements (including national mandatory standards) uniformly at poultry slaughter establishments. Although slight difference exists in the application of national standards among provincial CIQs, there is no significant variation so that the current practice can guarantee quality and safety of products.

In order to achieve the export of cooked poultry products to U.S. as soon as possible, AQSIQ will improve the training mechanism for inspection and supervision personnel of export poultry products, such as developing the training plan, defining the training manner, confirming the training class hours; AQSIQ has developed the *Inspection and Quarantine Manual for Poultry Exported to America* which makes uniform requirements for inspection procedure and inspectors of cooked poultry products export to U.S. and the *Microorganism Monitoring Program for Exported Poultry Products* which makes uniform requirements for microbial monitoring of export poultry products and processing environment, and will provide relevant trainings to the inspection staff of export meat products.

## **VI. Sanitation (Item 7 in the Audit Report)**

22. One area for improvement identified by the auditors concerned the manner in which the establishments conducted the aforementioned bi-annual assessments,.....However, a review of the audit records indicated that these reviews simply reflected additional monitoring of the sanitation program, as indicated by the identification of individual failures to adequately

maintain or clean equipment, rather than a systemic examination as to whether these activities and related results comply with the planned objectives, which are typically associated with the term "audit." Neither establishment personnel nor inspection officials interviewed were able to further describe the CCA's expectations for the type of audit methodology to be applied or the nature of conclusions reached, other than what is included in Section 8 of the referenced document. Consequently, this situation represents a need for further written guidance from the CCA to ensure that the implementation and verification of this national standard occurs as intended.

**Reply from PRC:** In fact, Clause 16.2 in the Ordinance No.20 enacted by AQSIQ requires relevant departments to supervise whether sanitation quality management system of enterprises operates effectively, while Clause 17.2 requires relevant departments to audit the establishments approved by importing countries at least once per half year. The said content already covers the audit requirements of internal audit. Based on the said function, PRC has developed training programs of internal auditors and sanitation registration auditors, which define steps and requirements of internal enterprise audit with corresponding written instructions.

AQSIQ will improve the training mechanism for inspection and supervision personnel of export poultry products, strengthen training of relevant inspectors before working, provide continuous training, make strict assessment, and enhancing capability of inspectors.

## **VII. Hazard Analysis and Critical Control Point System (Item 8 in the Audit Report)**

23. One significant finding identified by the FSIS auditors is that the national standard, GB/T 19538-2004, does not require food producers to establish measures to prevent recurrence in response to a deviation from the critical limit. This does not meet FSIS' equivalence criteria applied to foreign HACCP systems, which are based on the requirements found in 9 CFR 417.

**Reply from PRC:** The report of U.S. is inaccurate. Reasons are defined as follows:

(1) National standard GB/T 19538-2004, equivalent to CAC/RCP 1-1969, REV 3 1997, AMD 1999, conforms to international practice; it is applied and popularized in many countries in the world.

(2) Corrective actions outlined in Clause 3.4 of GB/T 19538-2004 defines that it is required to adopt corrective actions in the event of deviation from the critical limit. According to the definition of standard and the relevant training material [e.g.: the *Guide on Administration of Registering Chinese Exported Food* details such corrective actions (P108, China Foreign Economic Relations & Trade Publishing House, 2000, ISBN 7-8004-797-0)], CA contains the

meaning and requirement for adopting measures to prevent recurrence. In fact, 9 CFR PART 417.3 also make the requirement to establish corrective actions.

(3) FSIS inspected relevant systems of PRC in 2004 and 2005, including the establishment, implementation and maintenance of HACCP system and the requirements of Chinese standards and regulations. However, FSIS did not clarify that GB/T 19538-2004 did not comply with relevant requirements of FSIS in the final report.

(4) Most of authorities consider that the "Preventive measures" is included in the "Corrective Actions". For example, in the HACCP regulations of juice and seafood proposed by FDA, corrective actions are required to be taken in case of any deviation from critical limits, and are not specifically addressed which to take preventive measures against deviations from critical limits.

(5) This audit is to assess the equivalence instead of identity; In training materials of PRC and specific implementation of enterprises, corrective actions are adopted mostly, including measure to prevent recurrence.

(6) During the investigation of U.S., it is just an exception that certain enterprises do not establish the procedure of Prevent recurrence, but it does not mean that the standard has any problem.

In conclusion, AQSIQ think that GB/T 19538-2004 is equivalent to FSIS Part 417.

24. Furthermore, the auditors observed the HACCP plan at the slaughter establishments often included a critical control point (CCP) to address biological conditions, with "zero tolerance" for septicemic/toxic carcasses, fecal contamination, and several processing/trimming deficiencies including inflammatory process (cellulitis). As indicated previously, both the establishment and official inspection personnel were unable to identify lesions associated with cellulitis on a consistent basis. In this regard, the auditors' observation of affected carcasses at a point past the CCP constitutes a deviation from the critical limit. While related to the previous discussion, the significance of this finding as it pertains to this component concerns the CCA's responsibility to ensure that establishments set forth verification procedures for CCP monitoring, and to take appropriate enforcement action when establishment monitoring is not effective in identifying deviations from critical limits when they occur.

**Reply from PRC:** In fact, PRC defines that the inspection, identification, confirmation and treatment of pathological conditions such as inflammatory process belong to responsibilities of post-mortem veterinarians rather than the control scope of HACCP, and it is not set as critical limit. Thus, the deviation occurred does not belong to the deviation from critical limit.

*Inspection and Quarantine Manual for Poultry Exported to America* developed by PRC clarifies this point.

Pursuant to these Audit Reports of U.S. in PRC in 2004 and 2005, enterprises establish and implement HACCP system in accordance with relevant requirements and basically comply with requirements, but some specific problems still exist in enterprises. Some enterprises establish, implement and maintain HACCP inadequately, and some CIQ officials make poor management of CCP inspection procedure. These problems are caused by incapable inspectors. Nevertheless, relevant HACCP regulations and standards of PRC are basically equivalent to FSIS regulations. In addition, measures of mandatory enforcement are identical. Next, AQSIQ will improve the training mechanism for inspection and supervision personnel of export poultry products, such as developing the training plan, defining the training manner, confirming the training class hours, establishing the *Inspection and Quarantine Manual for Poultry Exported to America*, strengthening training of relevant inspectors before working, providing continuous trainings making strict assessment, enhancing capability of inspectors and guaranteeing the effect of supervision and inspection on enterprises.

25. The significant omission concerning preventive measures within the PRC's HACCP legislation, in addition to the lack of regulatory oversight identified at establishments, constitute systemic findings that compromise the CCA's ability to implement their HACCP requirements, and ultimately ensuring the consistent production of safe poultry products intended for export to the U.S. The failure of the food safety system to require preventive measures within the HACCP system may allow CCP deviations to repetitively occur. Consequently, the HACCP system is inadequately designed and does not provide a framework for addressing recurring deviations to be corrected and verified. Therefore, FSIS concluded that the PRC's inspection system does not meet the requirement for this equivalence component.

**Reply from PRC:** (1) The U.S.'s description about "the significant omission concerning preventive measures within the PRC HACCP legislation" is incorrect. The reasons are below:  
A. The national standard GB/T 19538-2004 equals to CAC/RCP 1-1969, REV 3 1997, AMD 1999, it conforms to the international convention, which is adopted and promoted by many countries around the world.

(2). In article 3.4 "corrective actions" of the national standard GB/T 19538-2004, it requires: if critical limit is deviated, corrective actions must be adopted. According to the definition of standard and relevant training materials [e.g.: the *Guide on Administration of Registering Chinese Exported Food* details such corrective actions (P108, China Foreign Economic

Relations & Trade Publishing House, 2000, ISBN 7-8004-797-0)], its corrective actions include preventive measures so as to prevent recurrence. In fact, 9 CFR PART 417.3 also provides requirements on adoption of corrective actions.

(3). The FSIS had checked the system of PRC in 2004 and 2005, which include establishment, implementation and maintenance of HACCP system, as well as the Chinese standards and rules, but its final report didn't indicate that the national standard GB/T 19538-2004 doesn't conform to FSIS.

(4). Most of authorities consider that the "Preventive measures" is included in the "Corrective Actions". For example, in the HACCP regulations of juice and seafood proposed by FDA, corrective actions are required to be taken in case of any deviation from critical limits, and are not specifically addressed which to take preventive measures against deviations from critical limits.

(5). This check is about "equivalence", not "identification", in the training material and specific execution case of PRC, most of which adopt corrective actions, including "prevention of recurrence".

(6). In American evaluation, some enterprises didn't cover the program of "prevention of recurrence", it is just single case, not the problem of the standard itself.

To sum up, the PRC's HACCP legislation has no omission concerning preventive measures.

(2) As the U.S.'s report mentioned in 2004 and 2005: "Enterprises establish and implement HACCP system as per relevant requirements, which meet the requirements basically, but enterprises do have some specific problems", what they did are not enough, some CIQ officers didn't well supervise and manage the test program on critical control points of the enterprise, which belongs to the ability of individual inspector, but the Chinese rules and standards about HACCP are equivalent to the FSIS, the compulsory measures are the same.

For the next step, AQSIQ will perfect the training mechanism for the inspection and supervision staff on poultry products, which includes formulating the training plan, determining the training methods, regulating the training hours, formulating the *Inspection and Quarantine Manual for Poultry Exported to America* strengthening pre-job training for inspectors and organizing training frequently, implementing strict feed back system, promoting the ability of inspectors so as to ensure the effects of supervision and inspection.

#### **VIII. Chemical Residue (Item 9 in the Audit Report)**

26. A post-audit analysis of a translated version of PRC's Method used to determine the amount of residue of carbadox, olaquinox and related metabolites in bovine and porcine liver and muscle tissues-LC-MS-MS indicated that the extraction procedure was not included in the

original document. In the absence of this information, and the fact that the method does not use poultry tissues, FSIS could not determine whether the method is equivalent for the detection of carbadox. In order to demonstrate method equivalence, FSIS requests that the CCA submit additional information regarding the extraction procedures related to the method originally provided, or an alternate method validated for poultry tissues.

**Reply from PRC:** the carbadox residue inspection method, adopted by Shenzhen inspection and quarantine authorities laboratory, is the standard operating procedure in laboratory based on GB/T 20746-2006 determination of the amount of residue of carbadox, olaquinox and related metabolites in bovine and porcine liver and muscle tissues -LC-MS-MS, that is, the determination of the amount of residue of carbadox, olaquinox and related metabolites in animal tissues - LC-MS/MS, this SOP is applicable for poultry & livestock products like chicken and chicken liver, etc, and it is examined and confirmed by AQSIQ as per *Quality Control Procedures For Residues*.

During evaluation of Shenzhen inspection and quarantine authorities laboratory, FSIS experts acknowledge the verification and confirmation procedure of the test method without doubt, and ask for the published standard text; in order to make U.S. fully understand the test procedure and methods of the poultry products in Shenzhen inspection and quarantine authorities laboratory, the Shenzhen inspection and quarantine authorities laboratory had provided the test methods SOP to U.S., which indicated the extraction procedure.

#### **IX. Microorganism Test Plan (Item 10 in the Audit Report)**

**27. The 5 paragraph on page 16 of the Audit Report: Major documents for official microorganism sampling and analysis of CCA are .....AQSIQ Order No. 26 2009.**

**Reply from PRC:** the information is incorrect here, the correct information is: *AQSIQ Order No. 26 2002*.

**28.** The findings associated with this latter review caused concern in that FSIS auditors observed inconsistencies in product sampling locations and sample collection techniques. In keeping with the findings outlined under Government Oversight, auditors observed that the CCA provided neither written guidance nor training to official inspectors to ensure uniform implementation of this standard across all provinces.

**Reply from PRC:** in fact, the sample collection techniques of PRC are based on GB16869-2005, there are no inconsistencies in microorganism product sampling locations

and sample collection techniques, which are subject to mandatory implementation across the country.

In terms of the sampling locations and sample collection techniques of the poultry microorganism test, PRC had translated relevant rules of U.S. and conducted training since 2004, and adopted new requirements when the rules were modified. When US perform audit in December 2010, PRC demonstrated the sampling process of a whole chicken at one slaughterhouse, which shows PRC had understood and had the ability to implement the requirements of U.S., the process will be implemented if products are exported to U.S.. FSIS might take the demonstration sample of salmonella and colibacillus (based on 9 CFR381.94) as the daily sample, the inspection and quarantine authorities of various provinces implement GB16869-2005 etc. with no significant difference.

PRC is willing to adopt the methods of U.S. so as to realize poultry export to U.S., and has formulated the *Microorganism Monitoring Program for Exported Poultry Products* to regulate the microorganism product sampling locations and sample collection techniques (See attachment 7 of the Monitoring Program) and develop relevant trainings.

29. The significance of the decree as it applies to this component relates to the commitment expressed by the CCA at the audit exit meeting, during which the PRC indicated it would adopt FSIS' requirements related to generic *E. coli* and *Salmonella* spp. as outlined in 9 CFR 381.94. Although on-site visits confirmed that translated versions of these requirements were disseminated to the official inspection staff, the limited awareness demonstrated during the on-site review, in addition to the inconsistent application of the PRC's own national testing standard raises concerns about the ability for official inspection personnel to implement FSIS requirements consistently without written guidance or training from the CCA.

**Reply from PRC:** in fact, PRC had translated 9 CFR 381.94 and conducted training since 2004, and adopted new requirements when the rules were modified. During inspection in some enterprises, U.S. had witnessed the official demonstration of the colibacillus and salmonella sampling methods of the whole chicken, which shows the Chinese inspectors understand the U.S.' requirements on colibacillus and salmonella.

In terms of the inconsistent application of the PRC's own national testing standard, FSIS might take the demonstration sample of salmonella and colibacillus (based on 9 CFR381.94) as the daily sample, the inspection and quarantine authorities of various provinces implement GB16869-2005 etc. with no significant difference, AQSIQ can ensure uniform

implementation of relevant requirements including national mandatory standards at slaughtering plant by inspection and quarantine authorities of various provinces, relevant safeguard measures had been stated in the above issues.

AQSIQ will perfect the training mechanism for the inspection and supervision staff on poultry products so as to realize export of cooked poultry products to U.S., which includes formulating the training plan, determining the training methods, regulating the training hours, *Inspection and Quarantine Manual for Poultry Exported to America* had been formulated, the inspection and supervision staff for cooked poultry products (exported to U.S.) are subject to uniform management, the inspectors are provided with pre-job training and frequent training, who shall be examined strictly, the ability of inspection and quarantine staff is uplifted; *Microorganism Monitoring Program for Exported Poultry Products* is formulated, which regulates the supervision on export poultry products and the test of microorganism in processing environment, and relevant training for inspection and quarantine staff will be developed.

30. The PRC has sufficient controls in place at the laboratories and government offices. The CCA did not provide written and uniform guidance to official inspectors ensuring standardized implementation of microbiological testing programs (i.e. product sampling locations, sample collection techniques, recording and evaluation of test results, and adherence to performance standards) at the establishment level. The CCA did not apply these food safety programs consistently throughout its inspection system and was unable to demonstrate that the PRC's inspection system affords the same level of protection as that provided by the U.S. system, as it pertains to the control of pathogenic microorganisms typically associated with raw poultry. Therefore, FSIS concluded that the PRC's inspection system does not meet the requirement for this equivalence component.

**Reply from PRC:** (1) in fact, the PRC's sample collection techniques is based on GB16869-2005, the microbiological product sampling locations and sample collection techniques are consistent, which is subject to compulsory execution across the country.

(2) PRC has uniform control system for inspection of raw poultry microorganism, U.S. had approved PRC's inspection and supervision system in the questionair examination, PRC execute the system of final product inspection and process supervision, U.S. put more emphasis on process monitoring, their methods are not the same, but the product safety can be ensured and achieve the same protection level.

PRC is willing to adopt the methods of U.S. so as to realize poultry export to U.S. as soon as possible, it has formulated *Microorganism Monitoring Program for Exported Poultry*

*Products*, which list the products and environments need to be sampled( including product sampling locations, sample collection techniques, recording and evaluation of test results, and conform to performance standards) and developed relevant training programs.

#### **X. Conclusion and Next Measures(Item 12 in the Audit Report)**

**31.** The assessment of actual establishment conditions in association with inspection records and interviews with AQSIQ officials indicated that these individuals were proficient in conducting verification and enforcement activities related to sanitation. However the requirements for internal audits conducted bi-annually by establishments in accordance with Section 8, Article 16 of AQSIQ Directive No. 20 were not clearly defined, thereby representing a need for further written guidance from the CCA to ensure that the implementation and verification of this national standard occurs as intended.

**Reply from PRC:** in fact, Section 2, Article 16 of AQSIQ Ordinance No. 20, regulates the requirements on supervision of effective operation of sanitation and quality management system of enterprises”, and Section 2, Article 17 regulates that the establishments approved by importing countries shall be audited once per half year (or in the production season) ”, which is also the requirement of internal audit of establishment. Based on the above function, PRC had formulated training course for internal auditor of enterprise and training course for official sanitation registration auditor , which describe the procedure and requirements on examination of internal part of enterprises, including corresponding written instruction.

AQSIQ will strengthen the training mechanism for inspection & quarantine and supervision personnel in terms of export of poultry products, relevant inspectors will be provided with pre-job training and frequent training, strict evaluation will be conducted to upgrade the capability of the inspection & quarantine personnel.

**32.** A post-audit analysis of a translated version of the PRC's method for the detection of carbadox indicated that the extraction procedure was not included in the original document. In the absence of this procedure, and the fact that the method does not use poultry tissues, FSIS could not determine method equivalence.

**Reply from PRC:** the carbadox residue detection used by libraries of Shenzhen inspection and quarantine authority is a standard library operation procedure made based on GB/T 20746-2006 the *Method for the Determination of the Residues of Carbadox, Olaquinox and Related Metabolites in Bovine and Porcine Liver and Muscle Tissues - LC-MS-MS Method*, i.e. the *Method for the Determination of Related Metabolites of Carbadox and Olaquinox in*

*Animal Tissues - LC-MS-MS Method - LC-MS/MS Method.* This SOP is applicable to chicken and its liver and other bird and livestock products and has been verified and confirmed in accordance with the *Residues Analysis Quality Control Guide* of AQSIQ.

FSIS experts understood and confirmed the determination methods and validation and confirmation procedures there during their review in libraries of Shenzhen inspection and quarantine authority. They proposed no objection and asked for the published text. Libraries of Shenzhen inspection and quarantine authority have provided SOP of determination methods, which defines the extraction steps.

33. The CCA provides only limited coordination of its inspection staff as it pertains to the issuance of written training materials and inspection manuals, relying extensively on the provincial CIQs to develop this guidance. However, the auditors noted that this autonomy resulted in significant variation in the application of national standards amongst provinces.

**Reply from PRC:** AQSIQ has prepared the *Inspection and Quarantine Manual for Poultry Exported to America* which shall be enforced by CIQs. China believed that slight difference between CIQs don't compromise the safety of products.

In order to export cooked bird products to the U.S.A. as soon as possible, AQSIQ has prepared *Inspection and Quarantine Manual for Poultry Exported to America*, which defines the uniform requirements on the inspection procedures and CIQ inspector for the cooked poultry products exported to the U.S.A., and prepared the *Microorganism Monitoring Program for Exported Poultry Products*, which defines the uniform requirements on the microorganism monitoring of exported poultry and the processing environment. AQSIQ will also launch relevant trainings for personnel responsible for supervising, inspection and quarantine of exported meat products.

34. The CCA lacks a standardized method to assign inspection personnel to slaughter facilities based on objective measurements such as production line rates, inspection workloads, or line configuration.

**Reply from PRC:** At present, AQSIQ delegate provincial CIQs to control the meat producing plants, and CIQs will appoint inspectors to the approved meat producing plants based on their production capacity, which is defined in the *Administrative rules on the Supervision, Inspection and Quarantine of Imported and Exported Meat Products*.

PRC uses U.S. arrangement of inspectors for reference based on production line rates, inspection workload, number of production lines, layout of production lines in a meat producing plant, and has prepared the *Inspection and Quarantine Manual for Poultry Exported to America*, which defines how to arrange inspectors in a processing plant(See III. Allocation of official inspection quarantine inspectors in appendix 1of the maunal).

**35. The CCA utilizes sorters paid by the establishment to conduct official inspection duties. This is a repeat finding from the 2005 audit. The inspection by CIQ veterinarians and establishment-paid veterinarians cannot ensure that pathological conditions can be detected and identified in time.**

**Reply from PRC:** (1) At present, under the supervision of official veterinarians, the ante-mortem and post-mortem inspections of export poultry in PRC are carried out jointly by CIQ-paid inspectors and establishment-paid inspectors who are approved by CIQ. In PRC, ante-mortem and post-mortem activities are conducted under the supervision of official veterinarians so that we can guarantee quality and safety of raw poultry products. At present, poultry processing and slaughter system of PRC has been approved by many countries who import poultry products from PRC. Cooked poultry products can be export to EU, Japan and other countries, and the trade goes smoothly.

In order to achieve the export of poultry products to U.S. as soon as possible, PRC is willing to adopt equivalent requirements for ante-mortem and post-mortem inspections of U.S. In the event of export of poultry products to U.S., PRC will comply with its inspection system to assign CIQ-paid inspectors to conduct ante-mortem and post-mortem inspections in processing enterprises that export poultry products to U.S. The Ministry of Agriculture released the *Administrative rules on Quarantine of Animal* (No. 6 Decree) on January 21, 2010 and the *Rules on the Quarantine of Slaughtered Poultry* on April 12, defining explicitly that the government-paid veterinarians are responsible for ante-mortem and post-mortem inspection. Such administrative rules are being enforced.

(2) AQSIQ develops the training programs for inspectors responsible for control of export meat products. During actual inspections, there may exist difference of capability among some inspectors. AQSIQ makes irregular flight inspections (inspection without advance notice) on the inspection and supervision situation of export meat products and the implementation situation of relevant regulations by local CIQs. If AQSIQ finds the variation of law enforcement and the difference of capability among inspectors, AQSIQ will provide training to inspectors promptly.

In order to achieve the export of poultry products to U.S., AQSIQ will further improve the training mechanism for inspection and supervision personnel of export poultry products. At present, AQSIQ is developing the training plan, defining the training manner, confirming the training class hours, revising the *Training Program in Supervision, Inspection and Quarantine for Exported Poultry and Related Products*, strengthening training of relevant inspectors before working, providing continuous trainings and making strict assessment. For microbial monitoring, AQSIQ has developed the *Microorganism Monitoring Program for Exported Poultry Products* to make uniform requirements for microbial monitoring of export poultry products and processing environment and will provide relevant trainings.

**36. When inspecting the packaging of poultry carcasses, auditors found that uropygial glands and heads are not removed from the carcasses before shipment. CCA did not fully understand the requirements of FSIS in 9 CFR 381.1 that the uropygial glands and heads of cooked poultry products should be removed.** (Postmortem activities conducted by CIQ veterinarians and establishment-paid inspectors did not ensure consistent identification of pathological conditions.)

**Reply from PRC:** In fact, CIQ officers do understand the provisions under 9 CFR 381.1 of the Code of Federal Regulations concerning the "ready-to-cook poultry". As early as in 2004 when U.S. FSIS officers investigated China's poultry exporting system, PRC has communicated with U.S. on ready-to-cook poultry. U.S. agreed that PRC can process poultry not in accordance with U.S. requirements on ready-to-cook poultry when processing the poultry not exported to U.S. PRC has made much training for inspectors since 2004 on U.S. laws and regulations on poultry products inspection. PRC do understand U.S. requirements on ready-to-cook poultry, and the cause for such misunderstanding is the poor communication or translation.

As long as the export to U.S. starts, in producing the raw poultry for heated poultry meat exported to U.S. (ready-to-cook poultry), the oil gland and head will be removed from the carcass before pre-cooling as required by U.S. laws and regulations. *Inspection and Quarantine Manual for Poultry Exported to America* prepared by AQSIQ has specified this item in detail (See 2.3 Slaughtering enterprises supervision, and Appendix 6 of the Manual).

**37. The national HACCP standard, GB/T19538-2004, does not require food producers to establish measures to prevent recurrence in response to a deviation from the critical limit. This does not meet FSIS' equivalence criteria applied to foreign HACCP systems, which are based on the requirements found in 9 CFR 417.**

**Reply from PRC:** this is untrue because:

(1) GB/T 19538-2004 conforms to CAC/RCP 1-1969, REV 3 1997, AMD 1999. It is consistent with the international practice and is adopted and popularized in many countries.

(2) The “corrective actions” under 3.4 of GB/T 19538-2004 defines that: corrective actions must be taken in case of deviation from critical limit value. According to standard definition and related training textbook [e.g.: the *Guide on Administration of Registering Chinese Exported Food* details such corrective actions (P108, China Foreign Economic Relations & Trade Publishing House, 2000, ISBN 7-8004-797-0)]. The corrective action (CA) refers to taking preventive measures to avoid reoccurrence. In fact, U.S. 9 CFR PART 417.3 also proposes the requirements to take corrective actions.

(3) U.S. FSIS inspected PRC systems in 2004 and 2005, including the establishment, implementation and maintenance of HACCP system as well as PRC standards, laws and regulations. However, the final report does not mention that GB/T 19538-2004 does not conform to related requirements of U.S. FSIS.

(4) Most of authorities consider that the “Preventive measures” is included in the “Corrective Actions”. For example, in the HACCP regulations of juice and seafood proposed by FDA, corrective actions are required to be taken in case of any deviation from critical limits, and are not specifically addressed which to take preventive measures against deviations from critical limits.

(5) This audit is about “equivalence” inspection instead of an “identity”. The corrective actions in training course and implemented by establishment include the preventive measures to prevent recurrence.

(6) During the U.S. inspection, just a few enterprises failed to cover those to “prevent reoccurrence”, and this is not a common phenomenon.

To sum up, PRC believes that GB/T 19538-2004 is equivalent to U.S. FSIS Part 417. PRC

38. The CCA did not consistently enforce HACCP verification requirements, or take appropriate action when establishment CCP monitoring did not identify deviations when they occurred.

**Reply from PRC:** As mentioned in 2004 and 2005 U.S. Audit Reports, “enterprises have established and implemented HACCP system in accordance with related requirements, which is substantially consistent with the requirement. But there are still some problems in certain enterprises”. Some enterprises did not do a good job in establishing, implementing and maintaining the HACCP, and some CIQ officers failed to completely supervising and managing the inspection procedures of key control points in the enterprise, which is caused by

individual's poor ability. But PRC's laws, regulations and standards on HACCP are substantially equivalent to U.S. FSIS' laws and regulations, and the compulsory execution measures are the same.

Next, AQSIQ will establish and perfect the mechanism on inspection and quarantine for exported poultry products and on training supervision personnel, including preparing training plans, making the training modes, determining the training hours, preparing the *Inspection and Quarantine Manual for Poultry Exported to America*, training related inspectors and making strict examinations and assessments to enhance the ability of inspection and quarantine personnel and ensure the effectiveness of supervision and validation for enterprises.

39. The CCA could not demonstrate uniform application of its microbial testing requirements for raw poultry. During the exit meeting, the CCA committed to implementing FSIS' requirements outlined in 9 CFR 381.94. In order to honor this commitment, the CCA is to demonstrate that it has taken the appropriate measures to ensure uniform application of these requirements as it pertains to sample collection and frequency, analysis of samples, recording and evaluation of test results, adherence to performance standards, and enforcement throughout its inspection system. The documentation provided should indicate the CCA's ability to implement the revised performance standards for raw poultry in accordance with the March 21, 2011, Federal Register Notice, and associated WTO notification on March 23, 2011 (notification number SPS/N/USA/2029).

**Reply from PRC:** In fact, PRC's sample collection is made in accordance with GB 16869-2005. Microbe sampling locations and sample collection techniques are the same throughout the whole country. PRC has a uniform control system to detect microbes in raw poultry. U.S. has recognized PRC's detecting and monitoring system during questionnaire examination and product quality can be secured.

PRC has started the translation of, and trainings based on the Code of Federal Regulations 9 CFR 381 since 2004, and updated new requirements as per changes in U.S.A. U.S. has witnessed the demonstration of whole-chicken sampling for escherichia coli and salmonella during the inspection of some enterprises, which indicates that PRC inspectors have understood U.S. requirements on escherichia coli and salmonella in slaughtering plants.

In order to start the exportation of poultry to USA as soon as possible, PRC is willing to adopt the U.S. requirements. China promise to follow the requirements of 9CFR381.94 and prepare the *Microorganism Monitoring Program for Exported Poultry Products*, which define the

exported poultry products and processing environment need to be monitored (i.e. product sampling locations, sample collection techniques, recording and evaluation of test results, and adherence to performance standards) and launch related trainings.

Attachment 2

OCT 06 2011

Comments on the Report of Inspection on Food Safety Management System of Heat-Processed  
Poultry Products in China– Received on September 27, 2011

**General Administration of Quality Supervision, Inspection and  
Quarantine of the People's Republic of China**

Extra Urgent

**Letter on Comments in the Report of U.S. Evaluation on Quality Management  
System of Heat-Processed Poultry Products in China**

Dear Director Andreas Keller:

We have received the report of the inspection on the food safety management system for poultry heat-processed product in China that is transferred by the U.S Embassy in China on September 8. Thanks for providing us with the opportunity of reviewing again.

In 2006, the United States had confirmed that the food safety management system of the pre-cooked poultry products in China could basically meet the requirements of the equivalence evaluation, and listed China as one of the countries that could export pre-cooked poultry products to the United States. However, actual trade has never occurred since the Congress of the United States has expressly forbidden the United States Department of Agriculture from using any allocation for any work related to the export of China's pre-cooked poultry products to the United States in its Agricultural Appropriations Bill for three consecutive years. From 2006 to 2011, China has promulgated a series of laws and regulations, such as the Food Safety Law and the Special Regulations of the State Council on Strengthening the Administration on the Safety and Quality of Food Products and made special efforts to deal with food safety issues, significantly improving the overall food safety system in China.

Unfortunately, you concluded in your inspection report that the special cases have influence on the system. For this situation, we think the reasons include: (1) The misuse of the equivalence evaluation, for example, on the issue of the sampling size of salmonella, the United States requested we use the exact same method as the United States. (2) The on-site communications between both parties are not sufficient. Take the inspection before working as an example, the United States thinks that the enterprise personnel performed the function of the related government departments. In fact, however, the Chinese Government has expressly defined the duties of the official inspectors. (3) The material and information exchange between both parties is not sufficient. The United States believes that the China does not have procedures for enterprise internal auditing. However, China has established the basic requirements,

procedures and techniques for enterprise internal auditing. And (4) The contingency of inspections. For example, the delegation of the United States has not found a processing procedure in the production flow chart of one producer, and attributed this to the insufficient HACCP inspection by the government to enterprises.

We sincerely want to continue to cooperate with you, such as providing you with supplementary information and the readjustment plans for related issues, and requesting you to revise the inspection report according to the comments and information provided by us.

We believe that the food safety management system of heat-processed poultry products in China could fully ensure the safety and hygiene of the poultry products exported to the United States. We hope that you could fulfill your promise to revise the inspection report and resume importing the products of related enterprises in China.

Please see appendix for the comments of China

We are looking forward to your reply. Your sincerely.

Appendix: Comments on the Report of Inspection on Food Safety Management System of Heat-Processed Poultry Products in China.

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Director of

Food Safety Division I

Import & Export Food Safety Bureau

General Administration of Quality Supervision, Inspection and Quarantine of the

People's Republic of China

September 27, 2011

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CC: Agriculture Department of the Embassy of the United States of America in China, and Economic and Commercial Council Department of the Embassy of China in the United States.

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Appendix:

**Comments on the Report of Inspection on Food Safety Management System of Heat-Processed Poultry Products in China**

Thanks for providing us with your inspection report on the food safety management system of heat-processed poultry products in China and the opportunity of reviewing again.

In 2006, the United States had confirmed that the food safety management system of the pre-cooked poultry products in China could basically meet the requirements of the equivalence evaluation, and listed China as one of the countries that could export pre-cooked poultry products to the United States. However, actual trade has never occurred since the Congress of the United States has expressly forbidden the United States Department of Agriculture from using any allocation for any work related to the export of China's pre-cooked poultry products to the United States in its Agricultural Appropriations Bill for three consecutive years. From 2006 to 2011, China has promulgated a series of laws and regulations, such as the Food Safety Law and the Special Regulations of the State Council on Strengthening the Administration on the Safety and Quality of Food Products and made special efforts to deal with food safety issues, significantly improving the overall food safety system in China.

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Our detailed comments are as follows:

I. The issues regarding the functions and training of official inspectors and

inspection manual that are mentioned in Page 9, 10, 13 and 18 of the report.

1. For the issues regarding sanitary inspection before working. The sanitary inspections in enterprises before working shall be conducted by inspectors of the enterprises. CIQ is responsible for verifying, recording and approving such inspections in daily monitoring and control. There is no such fact that the inspectors are paid by enterprises to perform the verification function.

We have provided you with the related information at the time of the first review and received your confirmation.

2. Issues regarding training materials and inspection manual. The pre-cooked poultry products exported from China are mainly inspected according to the Manual of Inspection and Quarantine for Exported Poultry Products and the inspection and quarantine requirements of the importing countries. Such materials are the major content of the trainings in China.

3. Issues regarding to trainings. The CAA trainings are used in China, and the examinations for official inspectors are organized by related local departments. We should learn from the experiences of the United States.

4. Issues regarding to Ready-to-Eat Products. Both parties have reached a common view in this regard.

## II. Issues regarding HACCP in Page 12, 13 and 16 of the report

5. Issues regarding to the definition of corrective actions. The GB/T 19538-2004, a national standard of China, equal to CAC standard (CAC/RCP 1-1969, REV 3 1997, AMD 1999), in which the corrective actions include using appropriate measures to prevent reoccurrence. China has expressly required in the safety, hygiene and quality management training materials for enterprises producing food products for exporting that the reasonable measures must be adopted to prevent the reoccurrence of deviation.

6. Issues regarding risk identification. China is formulating the guidance of risk analysis and control for heat-processed poultry products to guide enterprises to establish a HACCP plan, especially the risk analysis of the heat stabilization process and the identification and control of the monoplast wuchernd Listeria in the environment after heat-processing. This document will be provided to FSIS as soon as possible. The fact that one enterprise lacks a processing procedure in the production flow chart is an individual case, which cannot be considered official verification that HACCP controls of all enterprises is insufficient.

III. Issues regarding microorganism test in Page 14, 15 and 19 in the report.

7. Issues regarding the test of Listeria in the environment after the heat processing. The National Quality Inspection Bureau of China has formulated the unified Microorganism Inspection and Control Plan for Exported Poultry Products, which has expressly defined the methods for testing the Listeria in the samples and products in certain environment and the verification requirements. We agree to conduct the test according to the methods specified by the United States to verify the effectiveness of the controls of the enterprises.

8. Issues regarding to the official verification of the enterprise inspection methods. Both parties have reached a common view in this regard.

9. Issues regarding to the zero-tolerance of Listeria and Salmonella in food products. Both parties have reached a common view in this regard.

10. Issues regarding to the weight of test samples of Salmonella. Both parties have reached a common view in this regard.

OCT 06 2011

Attachment 3

Comments on Report of an Audit Conducted in The People's Republic of China Evaluating the  
Food Safety Management System Governing Production of Heat-Processed Poultry

– Received on October 6, 2011

Letter of submission for additional comment on US audit reports

Dear Dr. Andreas Keller:

It is appreciated that USDA FSIS has exchanged opinions with Chinese side on the audit reports of China's safety management system governing production of slaughtered and heat-processed poultry over the teleconference on 27<sup>th</sup>, Sept., and promised to publish the audit reports together with all the China's comments on your official portal website.

Attached please find the China's additional comments. We do hope that USDA FSIS can make a modification to the audit reports based on the comments.

Best regards

Attachment: Additional comments on the USDA FSIS audit reports

Director  
Food Safety Division One  
Import & Export Food Safety Bureau  
AQSIQ, P.R. China  
30<sup>th</sup>, September 2011

Attachment:

**Additional Comments on the US Audit Reports**

It is appreciated that the teleconference was arranged on 27<sup>th</sup>, Sept. and USDA FSIS reaffirmed to welcome additional comments from China on the audit reports.

Over the teleconference, US side mentioned that the equivalence of China's safety management system governing the production of slaughtered and heat-processed poultry to the US system is more than 90 percent. The Chinese side think that it is not proper to describe the individual problem find in individual establishment as "findings of greater systemic adverse impact", which is still remained in the final reports.

The Chinese side requests again that USDA FSIS can make proper modification to the final reports to reflect the factual situation of China's safety management system governing the production of slaughtered and heat-processed poultry.

## Letter for Comment Submission

---- *US Final Audit Report Over food safety management system in China*  
*Governing production of heat-processed poultry*

SEPT.27, 2011

Dear Director Keller:

Thank you for the final audit report on China's food safety management system governing production of heat-processed poultry, which was forwarded to us from your embassy in Beijing on September 8. The chance to comment again is much appreciated.

The United States confirmed in 2006 that China's food safety management system governing the production of processed poultry was basically in compliance with the US requirements on equivalence assessment and prepared to start the legislative process to permit the import of processed poultry from China. However no actual export from China has occurred because US congress prohibited USDA to use any appropriated fund on any process to facilitate the import of processed poultry from China in three consecutive years by enacting the *Agriculture Appropriations Act*.

China has enacted a number of laws and regulations since 2006, including the *Food Safety Law* and the *Special Regulations of the State Council on Strengthening the Supervision and Administration of the Safety of Food and Other Products*, and launched the program of special rectification on food safety. Thanks to the effort, food safety has been improved greatly.

We regret to see that individual problems are seen as having greater systemic adverse impact in the report findings. China believes there are several reasons behind it.

1<sup>st</sup>, misuse of equivalence assessment. For instance, the US requests China to draw the same sample size for salmonella test as US did.

2<sup>nd</sup>, inadequate communication during the on-site audit. Take the pre-operation inspection for illustration. The US side thinks establishment-paid inspectors take up food safety related official duties. In fact, China has clear stipulations over the duties of official inspectors.

3<sup>rd</sup>, inadequate exchange of documentation and information. The US side thinks there is no procedure governing establishment internal audit in China. The fact is China has in place the basic requirements, procedures and know-how on internal audit.

4<sup>th</sup>, incidental issues in the audit. The audit mission determines on an inadequate regulatory verification of the HACCP systems at all establishments on the mere basis that only a step was missing in the flow chart of one establishment.

China is ready for continued cooperation and provision of additional information and action plan for problem correction and again asks the audit report to be revised on the basis of comments and information supplied by the Chinese side.

China believes that its safety control system over heat-processed poultry guarantees the safety and wholesomeness of poultry intended for export to the United States. It is hoped the US side can honor the promise and revise the audit report to resume the import of products from relevant enterprises in China as soon as possible.

See attachment for detailed comments.

Look forward to your early response.

Best regards.

Director

Food Safety Division One

Import & Export Food Safety Bureau

AQSIQ, P.R. China

Attachment: Comments on report of an audit conducted in the People's Republic of China evaluating the food safety system governing production of heat processed poultry

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CC : Office of Agricultural Affairs, Embassy of the United States in Beijing, China

The Economic and Commercial Counsellor's Office, Embassy of P.R.C in the United States

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Attachment:

**Comments on Report of an Audit Conducted in  
The People's Republic of China Evaluating the Food Safety Management  
System Governing Production of Heat-Processed Poultry**

The Chinese side thanks the US for providing the report of an audit conducted in the People's Republic of China evaluating the food safety management system governing the production of slaughtered poultry and processed poultry, and the feedback on China's comments over report findings.

The United States confirmed in 2006 that China's food safety management system governing the production of processed poultry was basically in compliance with the US requirements on equivalence assessment and prepared to start the legislative process to permit the import of processed poultry from China. However no actual export from China has occurred because US congress prohibits USDA to use any appropriated fund on any process to facilitate the import of processed poultry from China in three consecutive years by enacting the *Agriculture Appropriations Act*.

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4<sup>th</sup>, incidental issues in the audit. The audit mission determines on an inadequate regulatory verification of the HACCP systems at all establishments on the mere basis that only a step was missing in the flow chart of one establishment.

***Specific comments:***

## **I. Official Inspectors' Duties, Training and Inspection Manual Mentioned in Pages 9, 10, 13 and 16.**

### *1. Pre-operation hygiene check*

The pre-operation check is done by establishment-paid inspector, and CIQ performs verification over pre-operation hygiene check and record review during regular supervision. It is not the case that establishment-paid inspector performs official pre-operation verifications.

Relevant information has been provided in the initial comment and confirmed by the US side.

### *2. Training materials and inspection manual*

Inspection for cooked poultry is carried out in accordance with *the Inspection and Quarantine Manual on Poultry for Export*, and inspection requirements imposed by importing countries, which are also the priority fields in inspector training.

### *3. Training*

The way of training in China is that CCA trains the trainers and provincial CA organizes training and examination of official inspectors. The way US does training is worthwhile learning.

### *4. Definition of ready-to-eat*

A common ground has been reached over this by the two sides.

## **II . HACCP in Pages 12, 13, and 16**

### *5. Definition of corrective actions.*

The national standards adopted in GB/T 19538-2004 is equivalent to the international standards of Codex Alimentarius Commission (CAC / RCP 1-1969, REV 3 1997, AMD 1999), in which "corrective actions" incorporates meanings of taking preventive measures against recurrence of deviations. It is clearly written in the training materials for food exporting enterprises on safety, wholesomeness and quality assurance that enterprises are asked to take measures to prevent the recurrence of deviation.

### *6. Risk identification.*

China is developing a guideline on risk analysis and control over heat-processed poultry meat to guide establishments on application of HACCP, which focuses on risk analyses over heat stabilization and identification and control of *Lister mono* in post-lethality environment. This guideline will be forwarded to FSIS as soon as possible. Certain step missing in the flow chart of one establishment is an individual case, and cannot suffice to be concluded as inadequate official verification over HACCP at establishments.

## **III. Microorganism Inspection in Page 14, 15 and 19**

7. *Lm test in the post-lethality environment.*

AQSIQ has developed *Microorganism Monitoring Program for Export Poultry Products* that is implemented throughout the country. It has clearly defined the test method for *Lm* in products and samples in post-lethality environment that can be used by establishments, and the method shall be verified by CIQ officials. China agrees to verify the effectiveness of control measures at establishments by using the US test method.

8. *Official verification of test method employed by establishment*

A common ground has been reached between two sides.

9. *Zero tolerance of Lm and salmonella in RTE food*

A common ground has been reached between two sides.

10. *The sample size for salmonella test*

A common ground has been reached between two sides.